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THE FEASIBILITY, PRACTICALITY AND COST OF A CERTIFICATE OF ORIGIN SYSTEM FOR GENETIC RESOURCES: PRELIMINARY RESULTS OF COMPARATIVE ANALYSIS OF TRACKING MATERIAL IN BIOLOGICAL RESOURCE CENTRES AND OF PROPOSALS FOR A CERTIFICATION SCHEME

Paper submitted by the United Nations University

Note by the Executive Secretary

1. At the request of the United Nations University (UNU), the Executive Secretary is pleased to circulate herewith, for the information of participants in the third meeting of the Ad Hoc Working Group on Access and Benefit-sharing, a paper on the preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme.

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

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The feasibility, practicality and cost of a certificate of origin system for genetic resources

Preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme

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Working Paper
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A report prepared as background information for the Ad Hoc Working Group on Access and Benefit Sharing of the Convention on Biological Diversity – meeting in February 2005, Thailand

Opinions and recommendations of the authors are not necessarily those of the case study contributors or their institutions.

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Foreword

The negotiation of an international regime on access to genetic resources and benefit sharing (ABS) is a pressing challenge for the international community. Responding to the call of the World Summit on Sustainable Development to negotiate an international regime on ABS within the framework of the Convention on Biological Diversity (CBD), the 7th Conference of the Parties to CBD has adopted a set of terms and reference to guide the Working Group on ABS when it meets to progress the debate on these issues, in Thailand in February 2005. A number of key issues to be addressed in the forthcoming debates will include the objectives for a regime, mechanisms and modalities for enhancing transparency, traceability and compliance with ABS agreements and national and international ABS law and policy. One potential tool which has received much attention as a means for achieving these latter aims relates to proposals for a mechanism for tracing the origin and legal provenance of biological and genetic resources. Based upon proposals made for what is now commonly referred to as a certificate of origin system the Conference of the Parties has called upon the Secretariat to CBD to investigate the feasibility, practicality and cost of certificates of origin, source and legal provenance.

During COP 7 in Kuala Lumpur in February 2004, UNU-IAS hosted a breakfast meeting for a group of interested institutions and individuals to explore the possibilities of carrying out a collaborative research project with a view to throwing more light on the potential and limitations relating to development of any certificate system. This meeting led to agreement between UNU-IAS and representatives of Royal Botanic Gardens, Kew, Smithsonian Institution, and the Instituto Nacional de Biodiversidad (INBio), for the preparation of a number of case studies, including a study on microbial collections to be carried out by UNU-IAS, which together serve as the basis for a comparative analysis on procedures for documentation of resources.

The report seeks to provide negotiators with insights into the realities of existing procedures for documentation of genetic resources, with a view to highlighting the opportunities and challenges to be faced in developing any system. The report demonstrates the need to find a balance between regulating commercial use and ensuring that basic science does not become the victim of overzealous guardianship of resources. Taking into account this research and based upon research being carried out in parallel by UNU-IAS the report suggests a potential role for different forms of certificates including certificates of origin, legal provenance and source, and suggests that utilization of all three forms of certificate may help support the adoption of a comprehensive regime.

UNU-IAS hopes this preliminary report will help to inform the Working Group on ABS' deliberations and looks forward to receiving input regarding the scope, focus and conclusions of this report with a view to enhancing our continuing efforts to support the international debate on these important matters.

We wish to acknowledge the important collaboration which this report represents and to thank the Royal Botanic Gardens, Kew, Smithsonian Institution, and INBio for their commitment to this work. We are grateful for the confidence they have shown in providing us with the insight into their operations and for the hospitality shown to UNU-IAS staff in their visits to each institution.

Thanks are also due to the MOSAICS project which has helped to create the environment and opportunities for UNU-IAS to carry out a preliminary analysis of microbial collections and their documentation procedures.

The United Nations University Institute of Advanced Studies (UNU-IAS) has within the framework of the Biodiplomacy Initiative developed an extensive program of research on issues relating to ABS. this has included policy reports on User Measures, ABS and Protected Areas, Bioprospecting in Antarctica, and the Role of Databases and Registers in the Protection of Traditional Knowledge. All of these studies, which are available online at www.ias.unu.edu, have been developed through collaborative research between the staff and fellows at UNU-IAS and external researchers.

This collaborative policy of UNU-IAS is in line with our mandate which seeks to bring about ever closer links between academia and the UN system. In line with this policy, the Biodiplomacy Initiative is committed to promoting collaborative research with a view to providing well researched policy papers to help inform and facilitate the ongoing negotiations for development of an international ABS regime. UNU-IAS welcomes and actively invites collaborations with a range of actors, institutions and organizations including governments, indigenous peoples and local communities, the private sector, NGO's, and research institutions.

A.H. Zakri

Director

Executive Summary

One of the goals of the Convention on Biological Diversity (CBD) is the fair and equitable sharing of the benefits from the use of genetic resources. The treaty recognizes national sovereignty over all genetic resources and provides that access to these resources be carried out on 'mutually agreed terms' (MAT) and subject to the 'prior informed consent' (PIC) of the country of origin.

The term 'certificate of origin' was originally coined in 1994 to describe a proposal for use of patent applications procedures as a means for ensuring the existence of PIC for use of genetic resources. The secretariat to the CBD was tasked by COP-6 to undertake information gathering and analysis of the feasibility of an international certificate of origin system as evidence of MAT and PIC for the use of genetic resources. As discussion of the proposal has advanced so too has debate about what should be certified and proposals have emerged for certificates of source and legal provenance as well. This led COP-7 in 2004 to decide to undertake further examination of an internationally recognised certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge as part of the negotiation of an international regime on ABS. Once again the feasibility, practicality, operational functionality and costs of any international certificate system were identified as the key issues to be investigated. Investigation will also address the potential role certificates might play in a system regarding the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights.

Certificates of origin may have a role in facilitating the continuous flow of genetic resources for commercial and not-for-profit uses while protecting the rights of the owners of genetic resources and associated traditional knowledge. Case studies of a range of plant, animal and microbial genetic resources were used as the basis for a comparative analysis of how different institutions are tracking the storage and dispersal of various kinds of genetic resources. These cases studies were based on major collections of biological resources around the world including the Smithsonian Institution (USA), the Royal Botanic Gardens, Kew (UK), INBio (Costa Rica) and a range of microbial collections. Together, the case studies and analysis sheds light on the feasibility, practicality and cost of a variety of potential systems for tracking genetic resources.

In this preliminary report, we present the results of these case studies together with a range of questions that must be addressed for any successful system, some potential models for how a certificate of origin system might operate, and a call for more analysis and potentially a pilot test of certificates to ascertain costs and benefits.

General Findings

Any certificate of origin scheme would need to protect the interests of resource providers without being so restrictive as to prevent desired flows of genetic resources for scientific purposes linked to the conservation objectives of the CBD. Access to genetic resources is also important for food security and to create commercial opportunities from which benefits may flow. Furthermore any system must not be so bureaucratic or costly that the transaction costs effectively consume potential benefits.

For non-commercial conservation uses, such as basic biodiversity research, there are many more international transfers of specimens compared to commercial users because no single country has the taxonomic expertise to identify the majority of organisms. In this sector, there are no monetary benefits to support an expensive tracking system and one option that has been proposed is to exempt these uses by creating a special category of uses exempt from certification. Care would need to be taken to ensure that any block exemptions did not create a loophole in the legal system that allowed genetic resources to flow to commercial uses via the exempt sector without renegotiation of an ABS agreement. An alternative to creating exemptions for classes of uses of resources would be to place trigger points where certificates

must be provided at stages in research and product development when it becomes clear that the use is no longer for basic research.

To some extent, technologies developed in other industry sectors may be applicable for achieving traceability of genetic resources. For some biological products like agricultural commodities there are quality assurance systems capable of tracking food from the farm to the supermarket. There already exist a range of international standards for biological products such as sanitary and phytosanitary (SPS) standards, food safety and labelling laws. For some other biological resources that are or have been traded, there is a certification system, the Convention on International Trade in Endangered Species (CITES). This is limited to border crossings of a selection of species when transferred among the 164 countries which are members of CITES and cases of illegal trade outside the system continue.

For biological specimens, the vast majority moved between countries are used for non-commercial research, not using the embedded genetic resources, or if they do, are using known genetic sequences for identification purposes. For new bioproducts discovery and creation, however, the supply chain arrangements are different, the value of the genetic resources component of the new product is poorly defined hence it can be difficult to demonstrate the benefit of an expensive tracking system, the timeframe from acquiring a resource to deriving any benefits may extend for decades or longer and in many cases it is more difficult to detect unauthorised uses of a genetic resource.

Tracing genetic resource transfers in biodiversity collections

The collection, movement, storing and transfer of biological and genetic resources are subject to a wide array of permitting and approval procedures. These involve extensive bureaucracy and human and economic resources to maintain, and involve a range of mechanisms for the documentation, monitoring and control of exchanges and use of resources.

A significant majority of biological and genetic resource collection activities and transfers are for non-commercial purposes related to basic science. Permitting procedures are already in place in a majority of countries to regulate the activities associated with such collection activities and the export of samples these procedures often involve costly and time consuming procedures involving a number of differing government agencies. Collections would benefit from the rationalization of access, collection, export and other permitting procedures.

Biological and genetic resource collections employ a wide variety of mechanisms to collate the resources they hold. These range from paper to electronic records and from batch to individual specimen records associated with specimens through barcode labelling. Collections would benefit from the rationalization of access, collection, export and other permitting procedures, if indeed it streamlined the system rather than creating a new layer of bureaucracy.

Large biodiversity collections such as Kew and the Smithsonian could potentially be overwhelmed by an inappropriate certificate system simply because of the numbers of specimens and transfers they handle. Kew's herbarium for example receives around 23,000 specimens per year from other collections and distributes around 18,000 specimens. To retrospectively certify its collection of 7.5 million specimens would be enormously costly. The Smithsonian deals with even larger numbers of specimens and its case study, like that of Kew, describes the practicalities of biodiversity research and the limitations that a certificate of origin system could potentially impose. In all of the case study institutions, international collaboration is essential to allow the basic biodiversity research that benefits resource provider countries and also contributes to the wider objectives of the CBD.

A standardized international system for documenting the origin, source and/or legal provenance of biological and genetic resources could help to facilitate access to genetic resources and transfers between and among collections. However, harmonisation of internal record keeping among collections globally would involve enormous investment of technological human and economic resources. Any system of

certificates of origin should therefore restrict itself to establishing a harmonised system for documenting genetic resource flows up to the point of entry into individual collections and at the point of exit. Any requirements relating to internal record keeping associated with biological and genetic resources should be minimal and only such as is necessary to ensure that the maintenance, use and transfer of resources to third parties is made in accordance with the terms and conditions under which they were obtained. Internal and external transfers should ensure that the relevant resources are always linked to the original certificate of origin.

A model certification scheme

One of the main beneficiaries of a standardized system for demonstrating the origin of biological and genetic resources and of rights to use them would be the private sector. A certificate of origin system which provides evidence of a clean title for use of resources would enhance the value of resources and create greater private sector interest in the natural products market. Any system should not unreasonably raise the costs of access or the time for processing applications.

Any system will need to apply to biological and genetic resources covered by the CBD and pre-CBD collections. Any system which does not apply to all transfers of biological and genetic resources will create loopholes which may undermine realisation of the CBD's ABS objectives. Failure to cover resources collected prior to the entry into force of the CBD may reduce the value of such resources for commercial users, lead to continuing controversy over biopiracy, and impede the development of a vibrant market in genetic and biological resources to support biotechnological development.

One area of much concern relates to the large amounts of genetic resources held in private collections, in universities and other research centres as well as by individual scientists. The origin of much of this material, especially where collected prior to the entry into force of the CBD, may be unknown and there may be little if any documentation to demonstrate the rights to utilise such resources. Any system should seek to develop mechanism which will facilitate the scientific sector to progressively bring their collections into the framework of a certification system without paralyzing ongoing research.

In order to respond to these three challenges, i.e. to establish clean title for resources obtained under the CBD, enable the continuing transfer and use of resources collected pre-CBD for which there is a clear legal title, and to progressively incorporate private collections utilised for non-commercial purposes while enabling such research to continue unimpeded, it is worth considering of the potential role of a variety of certificates including, certificates of origin, certificates of legal provenance and certificates of source. Use of a range of certificates could establish the basis for a comprehensive certification scheme.

A Certificate of Origin would most probably be granted by a national authority in the country of origin of biological and or genetic resources and would demonstrate that access was the subject of a valid ABS agreement.
A certificate of legal provenance could be issued by a biological collection, or a national authority in a country other than the country of origin, and would demonstrate the legal right to use resources for commercial and/or non-commercial purposes subject to compliance with the terms and conditions under which resources were originally obtained, if any.

A certificate of source would be provided to accompany any transfer of resources for basic non-commercial research.

One system recommended in this report for further investigation involves an online certificate for the access and benefit sharing agreement under which the genetic resources were obtained.

Certificates of origin and disclosure of origin

To the greatest extent possible a system of certificates should act as an incentive based mechanism to promote research activity. To this end check points for the presentation of certificates and the control of research should be reduced to a minimum. A system of certificates which operated as a form of shrink-wrap licensing to facilitate research activities, subject to the compliance with a standard set of terms and conditions including benefit sharing obligations could help to reactivate the natural products research industry, and generate greater benefit sharing opportunities. This would serve as an incentive for commercial users. Establishing incentives for non-commercial users would require identification of check points which are linked to the interests of scientific users, such as requirements to show a right to use resources as a condition for publication of scientific papers.

Disclosure of origin of genetic resources in patent applications is being adopted in an ever widening group of developing and developed countries. Obligations range from requirements to identify the origin or source of genetic resources to obligations to show evidence of compliance with ABS laws in provider countries or of prior informed consent for use of resources. To date such legislation has not directly addressed the situation regarding use of pre-CBD collections. This is something which will need to be rectified and it is proposed that any such legislation should require evidence of the origin of resources and the provision of evidence of the legal right to make use of resources for commercial purposes. A certificate system could serve to support such disclosure of origin requirements, with both certificates of origin and legal provenance serving as evidence of a legal right to use resources.

Costs associated with maintaining a certificate of origin system should be recoverable for national authorities in provider countries. In order to ensure that such costs do not unreasonably increase the costs of access, collection and export permitting procedures, countries should seek to rationalize their permitting procedures, with a view to avoiding unnecessary increases in overall costs of access. Where the issue of certificates of origin is linked to conclusion of ABS agreements the procedures for granting relevant certificate(s) of origin for all collection activities or for specific activities from time to time could be made automatic upon the approval of an ABS agreement, or perhaps upon the grant of an access permit and/or export permit by the national authorities.

Due to differing technical capacities and the status of many existing collections any system will need to employ a variety of mechanism for documentation purposes, Experience suggests any system should focus on a primarily paperless system.

The objectives of any system should be clearly worked out in advance of development of regulatory obligations for the use of any harmonised documentation procedures. Due care should be taken not to establish a system which will impede developing countries from effectively participating in the market for biological and or genetic resources or which will cause disguised barriers to trade or scientific research.

Further work is recommended to trial proposed certificate systems in a range of countries with different infrastructures and in different commercial industry sectors using biological resources.

The opinions and conclusions expressed in this report are those of the authors alone and do not necessarily reflect the opinions of the case study contributing authors or of the Institutions they represent.

Acronyms

ABS	Access to Genetic Resources and Benefit Sharing
ABSA	Access and Benefit Sharing Agreement
ATCC	the American Type Culture Collection
BCCM	Belgian Coordinated Collections of Microorganisms
BIOTECH	National Centre for the Genetic Engineering and Biotechnology Thailand
BPPT	Indonesia's Agency for the Assessment and Application of Technology
CABRI	The Common Access to Biological Resources and Information
CBD	Convention on Biological Diversity
CBR	Centre for Bioenvironmental Research
CBS	Centraalbureau voor Schimmelcultures (The Netherlands)
CETAF	Consortium of European Taxonomic Facilities
CITES	Convention on International Trade in Endangered Species
COP	Conference of the Parties of the Convention of Biological Diversity
DEFRA	UK Department of Environment, Food and Rural Affairs
DNA	Deoxyribonucleic Acid
DSMZ	Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (German Collection of Microorganisms and Cell Cultures)
FIRDI	Food Industry Research and Development Institute (Taiwan)
FRIM	Forestry Research Institute of Malaysia
ICBG	the International Collaborative Biodiversity Group Program
IDA	International Depository Authority
IFO	The Institute for fermentation (Japan)
INBio	Instituto Nacional de Biodiversidad (Costa Rica)
UNU-IAS	United Nations University Institute of Advanced Studies
IJSEM	International Journal of Systematic and Evolutionary Biology
INBio	the National Biodiversity Institute (Costa Rica)
IP	Intellectual Property
IPR	Intellectual Property Rights
ITS	Information Technology
LIPI	Indonesian Institute of Sciences
MAA	Material Acquisition Agreement
MAT	Mutually Agreed Terms
MOSAICS	Micro-Organisms Sustainable Use and Access Management Integrated Conveyance System

MoU	Memorandum of Understanding
MSB	Millennium Seed Bank
MSA	Material Supply Agreement
MTA	Material Transfer Agreement
NGS	Nimura Genetic Solutions
NITE	National Institute of Technology and Evaluation, Department of Biotechnology Japan
NRRL	Agricultural Research Service Culture Collection, National Center for Agricultural Utilization Research (USA)
OECD	Organization for Economic Co-operation and Development
PBRs	Plant Breeders Rights
PIC	Prior Informed Consent
R&D	Research and Development
RIKEN	Japan Collection of Microorganisms
SCBD	Secretariat to the Convention on Biological Diversity
SPS	Sanitary and Phytosanitary Standards
TK	Traditional Knowledge
TRIPS	Trade-Related aspects of Intellectual Property Rights
WDCM	World Data Center for Microorganisms
WFCC	World Federation for Culture Collections
WDCM	World Data Centre for Microorganisms
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1. Introduction

1.1 Background

Thomas Jefferson wrote in 1800 "The greatest service which can be rendered any country is to add a useful plant to its culture".[8] There were many who did great service in this context and during much of the last 10,000 years genetic resources such as crop plants have been moved freely around the globe with little or no regulation. For most people the majority of their diet now stems from resources that originated in other countries, and there is probably no single country that is totally self-sufficient in genetic resources for food and agriculture.

Jefferson's comments were made at a time when the attitude towards rights over genetic resources were that "possession is nine tenths of the law", and for the other tenth reliance could be made on the principle that biological resources were the "common heritage of mankind". Over time the practice of treating biological resources as common heritage caught on and was widely respected with an almost free flow of resources. During the last twenty years or so, advances in biotechnology have enhanced the utilization of genetic resources for conventional foods and other materials to higher-value products. The combination of genetic resources and biotechnology offers the possibility of an ever increasing range of products of immense commercial value based on the resources. This technological development has in turn catalysed efforts to develop mechanisms capable of capturing the greatest possible economic benefit from exploitation of genetic resources, including through the use of intellectual property rights (IPR). At the same time, there has been a counter movement to secure the interests of countries which are less able to commercially exploit their genetic resources but which wish to share in the benefits arising from its use. These trends, developed in an era which has seen the growth of international norm setting, in particular with regards to human rights law and the environment, as well as the expansion of IPR law and globalization of trade, have together strongly influenced the paradigm shift from a common heritage of genetic resources to the common concern of the global community to promote fair and equitable benefit sharing in return for continuing access to genetic resources.

The result has been the demise of the notion of a common heritage of mankind and the recognition of national sovereignty over genetic resources in the Convention on Biological Diversity (CBD). The CBD established the concept of countries of origin, being those within which genetic resources originated or where they have obtained their specific characteristics.

As the value of genetic resources has been increasingly recognized, in the years following entry into force of the CBD, both providers and users have found the existing governance framework to be inadequate for securing rights over the resources. Fledgling experiences in control of access to genetic resources have frequently been overly bureaucratic and restrictive to basic science, and out of tune with private sector commercial reality. There are those too who see all attempts to regulate ABS as merely playing into the hands of big business interests, and who see no possibility of equitable bioprospecting arrangements in a world where IPRs rule. Efforts to advance the implementation of the CBD through the development of a set of voluntary Guidelines on access to genetic resources and benefit sharing (ABS), in 2002, were quickly followed by a call for negotiation of an international regime on ABS, in the Plan of Implementation of the World Summit on Sustainable Development, later the same year. The Conference of the Parties to CBD, has adopted a decisions setting out the terms of reference for the negotiation of this international regime, and negotiation will begin in earnest at the Working Group on ABS in the early 2003.

[8] Juma, Calestous and Vicente Sanchez, Biodiplomacy: Genetic Resources and International, Relations, ACTS Environmental Policy Series No.4, ACTS Press, Nairobi, 1994.

Developing a framework for negotiations and advancing the development of an international regime is a complex issue, negotiators have already begun trying to identify a number of key areas of focus for the process. Amongst these the issue of objectives of any regime and the manner for ensuring compliance are seen as particularly important. One issue which has also found its way to the top of the negotiators agenda is the matter of how to ensure that in any regime it will be possible to identify the origin/source of resources and of the legal right to use them, an issue which is at the heart of securing realisation of the CBD's objective of fair and equitable benefit sharing. One tool which has become the subject of much attention relates to the possibility of establishing some form of standardized international system of documentation to assist in monitoring the commercial use of genetic resources and traditional knowledge. In recent years growing attention has been drawn to proposals for what has been termed a 'certificate of origin' system, to facilitate tracing of genetic resource flows and identification of the existence of prior informed consent (PIC) for their use.

UNU-IAS has prepared this study to help negotiators consider the potential role of documentation of genetic resource transfers as a means for securing the CBD's ABS objectives; providing an insight into the potential modalities for a certificate of origin system; and, drawing attention to the challenges associated with developing any such system. As part of the process for development of the report UNU-IAS has sought the preparation of a number of case studies from a number of biodiversity collections in order to facilitate a more informed of these issues.

The present study combines the results of two research projects carried out by UNU-IAS. PART I is comprised of a group of case studies of documentation of biological and genetic resources carried out in collaboration with a variety of biodiversity collections, and includes a comparative analysis of the main characteristics of their documentation procedures. Dr. David Cunningham had primary responsibility for coordination of these case studies and preparation of the comparative analysis. PART II of the study discusses the potential framework, nature, and modalities for a certificate of origin scheme. This work which is informed by the cases studies, builds upon research by UNU-IAS staff and the proceedings of a number of recent national and international workshops which have been held on certificates of origin and ABS Governance[9]. A final section sets out preliminary conclusions of both, PART I and PART II.

Due to time constraints the case studies and the analysis of potential modalities for a certificate regime have been developed in parallel, as a result it has been impossible for the collaborating case study authors to carry out a full analysis of the implications of the certificate options discussed in PART II, in their studies. It is intended that in a future iteration of this report a more comprehensive analysis will be carried out and presented in a final report to be prepared for a subsequent meeting of the Working Group on Access and Benefit Sharing.

1.2 Difficulties in implementing ABS governance

In the decade since the CBD came into force countries have made limited and uneven progress in enacting legislation to implement its access and benefit sharing (ABS) provisions. One reason is that while virtually all countries are providers of genetic resources, few see themselves as being responsible for adopting measures to ensure that use within their territory corresponds with the rights and interests of countries of origin and indigenous and local communities. As a result legislation has focused on restricting access and not on maximising the benefits to be shared (Falcon and Fowler 2002). One result has been a heavy impact upon the activities of the scientific community, with some regulations making it

[9] Recent workshops have included Yokohama roundtable on certificates of origin, organised by UNU-IAS July 2004; Washington Roundtable on Certificates of Origin, organised by UNU-IAS and the Smithsonian Institution, September 2004; International Workshop of Experts on ABS in Cuernevaca, Mexico organized by Environment Canada and CONABIO, October 20004, and the 2nd Paris Roundtable on ABS governance: Feasibility, Practicality and Cost of Certificates of Origin, organized by UNU-IAS, IDDRI and UCL, November 2004.

virtually impossible to carry out basic research and to collect or legally move new or existing specimens. One of the most highly affected groups have been those carrying out taxonomic and systematic work, which has serious implications for basic research on biological resources and the variability of life, as well as of the use of such science for conservation purposes.

Defenders of strong ABS regulation have consistently pointed to a perceived lack of action on behalf of those countries, primarily in the developed world home to the vast majority of the world's biotechnology, agro-industrial, pharmaceutical and natural products industries. With a view to promoting what developing countries have seen as a greater balance in responsibility for securing the CBD's objectives on ABS, suggestions were frequently made for the adoption of what has been termed "user measures".

Since the idea of user measures was first promoted in the late 90's there has been strong resistance from developed countries to the proposal that they should assume a responsibility for ensuring that use of genetic resources within their territories was subject to compliance with requirements on prior informed consent in the laws of countries of origin. They have rightly argued that all countries are both providers and users of genetic diversity, and suggested that therefore they should carry not special obligations. However, during the 6th conference of parties (COP-6) to the CBD in The Hague in 2002 the concept of user country obligations was finally recognized and accepted and inserted into the Bonn Guidelines on ABS. Although the guidelines are non-discriminatory it is recognised that the responsibilities on user measures fall to be responded to in the short term by countries with highly developed biotechnological, pharmaceutical and agricultural industrial sectors. These provisions apply equally to both developed and developing countries and those developing countries which are aggressively promoting their biotechnology sector, as well as of other industrial sectors, should also take measures to ensure that the use of resources within their territories complies with the CBD's objectives.

The Bonn Guidelines on ABS provide a detailed outline of proposed steps and processes for development of functional ABS regimes and agreements. While the Guidelines emphasise the obligations of users of genetic resources under the CBD many developing countries left COP-6 with a feeling that there remains an imbalance between providers and users in negotiating ABS agreements and that without a legally binding international instrument to regulate ABS equity will not be achieved. This is partly because there is no enforcement mechanism and no way of monitoring whether benefits have been shared equitably. This concern led to the call for negotiation of an International ABS regime by the World Summit on Sustainable Development.

As work has gone on to examine the potential mechanisms available to enforce compliance with ABS agreements, it has become clear that there is a need for a system to track where genetic resources have come from and to provide evidence of compliance with regulations on prior informed consent (PIC) and mutually agreed terms (MAT) for the use of the resources. There are already numerous mechanisms which provide means for tracking at least in part the flow of genetic resources, including through bioprospecting, export and import permits, passport data held by collections, ABS agreements, etc. However, there is, as yet, no harmonised system which can provide easily recognisable evidence of the source/origin of resources and/or of the legal right to use such resources. A proposal for some form of tracking system was made in the months following the entry into force of the CBD, when it was suggested that some form of CITES type permitting system might serve to assist in tracking genetic resource flows[10].

Concern that a comprehensive CITES type system of permits might prove unwieldy and cost inefficient led to a proposal for a market based system which would move the responsibility for providing a certificate of origin to the end of pipe in the product development chain, rather than requiring its emission at the date of collection of the resources[11]. The idea being to create an incentive for users to utilise

[10] Downes 1993
[11] for more detailed discussion of this issue see Tobin 1994, 1997

resources for which there was a clean title by shifting the burden of proof regarding the right to use resources from the provider to the user. This proposal suggested the need for establishment of a standardised international system of harmonised documentation to provide evidence of the origin of genetic resources and of rights to use them. The term utilised to describe such documentation was "certificates of origin"[12]. More recently the use of the term certificates of origin has been used to describe both end of pipe monitoring and point of collection documentation of resources.

1.3 A possible role for certificates of origin

The term 'certificate of origin' was originally coined in 1994 to describe a proposal for use of patent applications procedures as a means for ensuring the existence of PIC for use of genetic resources[13]. The original concept was that the patent offices should require the disclosure of the origin of genetic resources and associated traditional knowledge as a condition for receiving applications for grant of patents. It was suggested that establishment of a standardized 'certificate of origin' which would act as evidence of prior informed consent would exempt patent officers from the need to examine all of the documentation related to an ABS agreement to verify compliance with the CBD. It was suggested that such requirements could extend to product approval procedures[14] , and act as an interim measure to protect the rights of indigenous and local communities over their traditional knowledge[15].

The term certificates of origin was first introduced into the international negotiation process in the Report of the First Expert Panel on ABS, convened by the secretariat to the CBD (SCBD), in Costa Rica in 1999. The concept was advanced in the discussion of the First Working Group on ABS, held in Bonn in 2001, and the SCBD was tasked by COP-6 to undertake further information gathering and analysis of the feasibility of an international certificate of origin system as evidence of mutually agreed terms (MAT) and PIC for the use of genetic resources. As discussion of the proposal has advanced so too has debate about what should be certified and proposals have emerged for certificates of source and legal provenance as well. This led COP-7 in 2004 to decide to undertake further examination of an internationally recognised certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge as part of the negotiation of an international regime on ABS. Once again the feasibility, practicality, operational functionality and costs of any international certificate system were identified as the key issues to be investigated. Investigation will also focus on the potential role certificates might play in a system regarding the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights.

Despite several preliminary investigations and many informal discussions at international meetings, there is still no clear understanding of how a certificate of origin system could operate in practice, or what should be the scope or nature of any such system. A review of user measures for ABS was published by UNU-IAS in 2003 and highlighted the potential role of certificates of origin (Barber *et al.* 2003). In this policy brief, a preliminary list of the information that may perhaps be included in a certificate of origin was proposed to include:

- Particulars of the provider and user;
- Particulars of the indigenous or local communities parties to the agreement;
- Details of genetic resources or traditional knowledge;
- Details of the approved use which may be made of the resources;
- Details of any restrictions on use;
- Period of the agreement;

[12] Ibid.
[13] Ibid.
[14] Tobin 1997
[15] Tobin 1999

- Conditions relating to transfer of rights to third parties; and
- Details of the issuing authority (Barber *et al.* 2003).

One potential embodiment of a certificate of origin may be likened to a passport that accompanies genetic resources, either through their entire history from collection to use ('cradle to grave') or only for certain transactions such as patent applications or product approvals. It has also been suggested that certificates may play a role in monitoring transboundary movement of genetic resources with customs authorities taking a role in controlling illegal flow of resources (Figure 1).

The term certificates of origin has been some as problematic, implying as it does a link with countries of origin of genetic resources as defined under the CBD. Attention has been drawn to the complexities of identifying the origin of many resources which have been in circulation for decades, if not centuries. Alternatives terms have been suggested such as a 'certificate of source' or a 'certificate of legal provenance', each of which carries its own potential interpretation. This paper will discus these various proposals in more detail in Part 2, proposing that in the development of any regime there may be good reason to explore the possibility of developing a comprehensive regime in which various types of certificates serve to identify the origin, relevant source and legal provenance of resources and the rights to use them.

Part 1 of the report focuses on practical aspects of handling biological and genetic resources in biodiversity collections. This analysis has been strengthened by the preparation of a number of independent case studies by major collections of biological resources around the world including the Smithsonian Institution (USA), the Royal Botanic Gardens, Kew (UK) and INBio (Costa Rica). Case studies of a range of plant, animal and microbial genetic resources are being used by UNU-IAS as the basis for a comparative analysis of how different institutions are tracking the receival, storage and dispersal of various kinds of genetic resources.

PART I - Tracking biological and genetic resources

2. Case studies of resource documentation

2.1 Methods

Discussions regarding preparation of a set of collaborative case studies of processes for documenting the management of genetic resources by major collections were initiated at a Roundtable Discussion on certificates of origin, convened by UNU-IAS on the margins of COP-7 of the CBD in Kuala Lumpur. Subsequently, a common framework was developed to facilitate a comparative analysis of case studies of different types of genetic resources used by different sectors. Figure 1 illustrates both the basic case study framework and a conceptual model for a certificate of origin showing potential checkpoints that may be considered.

Case study contributors were asked to provide an authored or co-authored section of a wide ranging report on certificates of origin. The case studies were used to support comparative analysis of various systems in place around the world for tracking genetic resources.

The case study contributors were asked to:

1. Briefly describe the kinds of genetic resources their collection is dealing with.

2. Describe the supply chain for the material including where it comes from, where it goes to and the intermediate stages, transaction points, types of organizations involved etc. and the uses for the material both internally and by 3rd parties which material is provided to.

3. Describe the mechanisms and documentation in place to identify and track the movements of material that enters and leaves the collections, and any internal transfers that take place.

4. Discuss the estimated costs of each kind of paperwork or data processing involved per transaction/change of custody, per specimen, per batch and/or other relevant measures for different kinds of material.

5. Describe the practical aspects of tracing material back to its source and forward to its end uses, perhaps with examples of successful and unsuccessful attempts to draw out the limitations of what and how far material can be traced and how much it costs to trace.

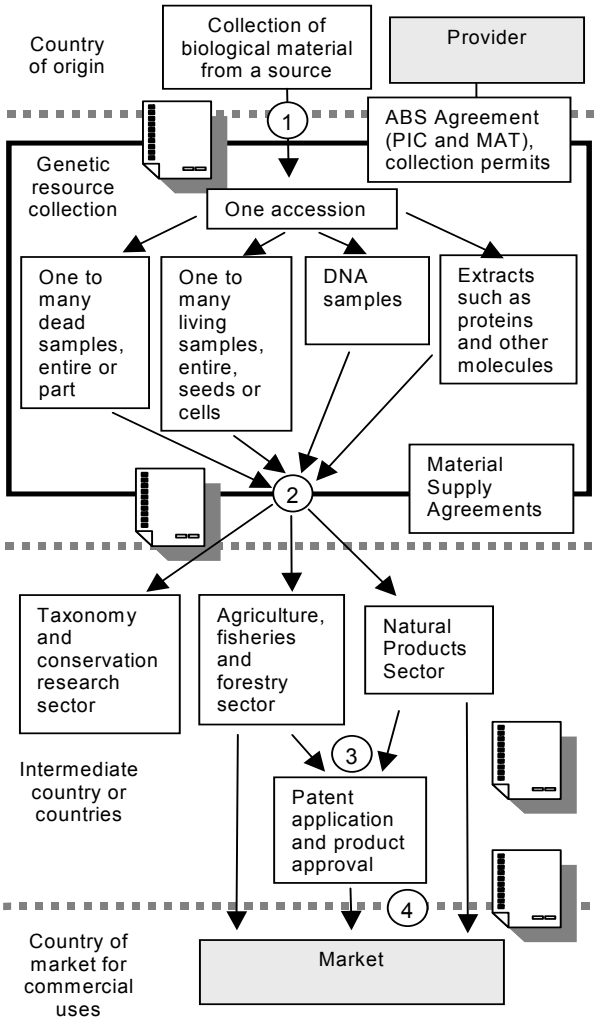

Figure 1. A simplistic rendition for genetic resource flows showing some potential check-points for a certificate of origin. Transfers of genetic resources may pass through one or more national borders (dotted lines). Biological material is acquired by a company or institution at Phase 1 and partitioned into different types of resources; at phase 2 some of these may be provided to 3rd parties, some do biodiversity and conservation research and others may develop commercial products. A new product could be patented or registered for a commercial use at phase 3 and traded at phase 4.

2.2 The Smithsonian Institution: The life of natural history museum specimens

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2.2.1 Introduction

The natural history museums of the world are a mixed bag—from small, local, organizations dedicated to single taxa to global reference collections. However, the vast majority of them pursue basic science research on taxonomy (the describing and naming taxa) and systematics (studying the evolutionary relationships between species). The museums of the world have collaborated for centuries—sharing collections, loaning specimens for research and education, and collaborating in the field and the laboratory. Movement of specimens across borders is an important aspect of access. It is fundamental in taxonomy and systematics. The effect of access and benefit sharing (ABS) processes has been to raise barriers with serious implications for these fundamental and necessary collaborations by making it difficult and in many cases even impossible to collect or legally move new or existing specimens. Perhaps no group of organizations or researchers has been more impacted by the ABS discussions under the Convention on Biological Diversity (CBD).

This case study will explain how basic research organizations engage in collecting work, and why ABS regulations should be able to be modified to facilitate taxonomic, systematics and ecological research. Burdensome, regulatory systems impose costs that far exceed the benefits, and even more importantly, transfer those costs to the provider or/and organizations least able to bear them. ABS systems that do not recognize how basic science works negatively impact the work of these scientists, taxonomists and systematists, who the leaders of the world have acknowledged as being too few already.

2.2.2 Demystifying the use of specimens and collections

Scientists unanimously agree that most of the species of the world are not yet described and named. Basic discovery, analysis, and naming of the biota is the core work of natural science collections organizations (not all are museums, but we use the generic term museums to cover them all). The first step in this research is to access, e.g. find, discover, or locate unknown biodiversity *in situ*. Historically, collectors gathered many specimens in the field. Field trip costs (financial, personnel, logistical) were sufficiently high that scientists collected as much as they could, knowing that some specimens would be studied only decades later. Indeed the majority of baseline information on most of the world's biota and ecoregions resulted from subsequent study of these "latent" collections.

The increased ease of international travel and heightened sensitivities to large collecting trips, have made scientists in many specialties calculate carefully just how many specimens are necessary to answer the questions at hand, be it taxonomic, systematic or ecological. Therefore, researchers nowadays seek to limit the numbers of specimens collected. The minimal collection size necessary for taxonomic research varies widely with each taxonomic group. For lesser known groups such as invertebrates, relatively more specimens are required to solve taxonomic problems; for well-known groups such as mammals or birds, only one or a few specimens may effectively answer the question posed.

Why are many specimens required? Why is one specimen generally not enough? No matter how similar, two specimens always differ in some characteristics (morphological, physiological or genetic) and those differences sometimes denote distinct species. The only way to tell if such differences are species- or population-level variations (such as the differences between different people) is to examine a sufficiently

large series of specimens from throughout the species range. For example, ideally, the series should reflect variation in males, females and juveniles. The series enables full description of intraspecific variability and precise differentiation of closely related species. Such work is crucial to prevent misidentifications and to discriminate among cryptic, sibling, or semi-species properly.

Such comparisons require loans from other museums. For example, a potentially new butterfly species from Brazil will probably be identifiable to family and genus based on existing literature. Furthermore, the literature may document a very similar butterfly species known only from Peru and Costa Rica and may also indicate which collections may house those specimens. The Brazilian specimen must be directly compared with to the Peruvian and Costa Rican specimens to resolve its status, requiring a scientist to either visit those museums holding the other specimens or request a loan. Loans are obviously far more cost effective and efficient than visits and thus the free movement of specimens between taxonomists is crucial to the continued existence of this science. Where ABS rules either do not make allowances for such exchanges or impose increased costs and uncertainties on the borrowing or loaning of specimens for study, taxonomic research is impeded. Each potentially new species encountered during fieldwork requires such comparisons, thus necessitating further loans and borrowings. On average, the Smithsonian requests about 327,000 loans from other collections, and sends about 170,000 loans to colleagues in over 100 countries annually. If taxonomy is going to continue within its existing budget and maintain productivity, a mechanism for material exchange that is clear, expeditious, and cheap, is absolutely essential.

Smithsonian loan policies and forms make it clear that loans are only for non-commercial research. As ABS discussions evolve, the Institution continuously examines its procedures to make certain that they conform to the terms and conditions of specimen movement. The internal tracking systems (transactions databases) have been modified over time to incorporate the needs of tracking specimens from collection through use.

Transaction costs of specimen movement must however be minimized. Some current proposals for tracing genetic resources would require approval from country of origin/source for all transactions; such regulations on purely taxonomic transactions would be time consuming and costly in terms of human resources and work paper and should be avoided whenever possible. Clearly, heightened scrutiny, mutually agreeable terms from the country of origin/source, and clear mandates are fully appropriate when material is requested for commercially oriented research.

2.2.3 The Smithsonian's collections

The Smithsonian Institution is comprised of 18 museums and multiple research units. The vast majority of biological collections are held by the National Museum of Natural History (NMNH) which counts over 125 million collection items and associated archival materials among its holdings (Table 1). They range from DNA to cultural artefacts, from microfossils to elephants, from stone tools to meteorites.

Table 1. Smithsonian National Museum of Natural History collections: Number of objects or lots of each type, the percentages of objects on exhibit and the percentages of objects owned

Department	Number of Objects/Lots
Department of Botany	4,600,000
Department of Entomology	30-35,000,000
Department of Zoology	
Division of Invertebrate Zoology	34,000,000
Division of Vertebrate Zoology	9,700,000
Totals	**83,300,000**

The **National Herbarium** was founded in 1848 when the first plant collections were accessioned from the U.S. Exploring Expedition (the Wilkes Expedition). Since then, holdings have increased to 4.6 million algae, bryophytes, lichen-forming algae, pteridophytes, gymnosperms, and flowering plants. The Type Collection contains more than 90,000 specimens and is supported by the largest verified database of types in the world. Supporting collections include the world's second largest wood collection, a liquid-preserved collection of seeds and fruits, frozen tissue collections for use in molecular research, anatomical and palynological microslide collections, and a greenhouse research collection comprising almost 10,000 square feet.

The **National Entomological Collection** includes more than 30 million specimens from all regions of the world and is one of the three largest insect collections in existence. Material from the Western Hemisphere is especially well represented. There are nearly 100,000 primary types. Apart from insects, extensive holdings of spiders, mites, centipedes, millipedes, and similar invertebrates are maintained.

The **Invertebrate zoology** collections (34 million specimens) focus largely on marine and freshwater animals, such as sponges, sea stars, corals, worms, molluscs, and crustaceans. While all parts of the world are represented, most of the collection is from U.S. coastal waters. The **Vertebrate Zoology** collections are divided in several categories. The collections of amphibians and reptiles include more than 500,000 specimens. The major geographic strengths are in the Neotropics and the Pacific. The fish collections include more than 8 million specimens and contain the largest holdings of Indo-Pacific marine shore fishes, one of the largest collections of South American freshwater fishes. The bird collections include more than 600,000 specimens representing 85 percent of known birds. And the mammal collections are the world's largest with more than 580,000 specimens.

These collections are in different stages of electronic cataloguing. Many of the historic parts of the collection are only documented in log books or catalogue cards. Currently about 11% of the records are in computer databases, with varying degrees of completeness.

In addition, NMNH has important and unique **federal partnerships**, begun in 1881, in which components of the systematics research units from the U.S. Departments of Agriculture, Commerce, Defense, and Interior are housed at the NMMH and their collections are integrated within the museum collection. The Smithsonian is a CITES registered organization for sending and receiving CITES listed materials.

2.2.4 Categories of collections

NMNH holds its collection in several different types of conditions and uses. The collections are categorized by different levels of care, documentation, and long-term stewardship. Permanent collections of intrinsic value to art, history, science, or culture are held and curated on a permanent basis (125,919,014 objects) (Table 2). Educational collections are held and recorded separately from the permanent collection for use in exhibitions and public programs (37,100 objects) and research collections are held for comparative and study purposes and include collections pending accession, living collections, genetic collections, and other unaccessioned research materials (25,407,417 objects).

Table 2. Smithsonian National Museum of Natural History collections categories of collections and number of objects for each type of collection

Categories of collections	Number
Permanent	125,919,014
Pending accession	25,000,000
Temporary custody	38,457
Public programs/ education	42,700

Incoming loans	327,528
Living collections	22,500
Genetic resource collections	25,000
Totals	**151,336,699**

The 25 million specimens listed as pending accession are largely a planktonic collection at the Invertebrate Zoology transferred upon the closing of the Smithsonian Oceanographic Sorting Center (SOSC), circa 1991. Specimens and objects which are sent to NMNH for vital forensic, identification, or other professional analysis, but are not intended to be added to the collections are hold under temporary custody and are generally returned to another agency following analysis. Approximately 20,000 living arthropods are part of the living collections and are used in exhibitions and demonstrations or kept for workshop and other outreach use in the Insect Zoo; 55 living soft corals in the Discovery Room; 130 living fish maintained for research in Vertebrate Zoology; and approximately 1500 plants maintained for research in the MSC greenhouses. And there are tissue sample holdings in the Departments of Zoology, Entomology, and Botany, and of the Laboratory of Analytical Biology.

2.2.5 Categories of transactions

When specimens enter the museum, they are subject to a series of inspections and decisions. Do they carry appropriate paperwork—permits, agreements, and shipment documents? Do they harbour any pests? Do they need special handling? Are they for permanent acquisition, on loan for a period of time, to be disaggregated and redistributed to other collections, or for education and display purposes? (Less than 0.1% are ever for display.)

Accessioning is the creation of an immediate, and permanent record utilizing a control number for an object or group of objects added to the collection from the same source at the same time, and for which the museum has custody, right, or title (Table 3). An accession record include the accession number; date and nature of acquisition (donation, exchange, field collection, etc); source; brief identification and description; provenance; and name of staff member recording the accession. However this is not a complete record of the object—that information needs research and identification by a specialist. NMNH acquired and accessioned **221,155** items in 2001, **1,111,324** items in 2002 and **129,864** items in 2003, most as gifts, exchanges, field collections, purchases, or transfers from government agencies.

Table 3. Smithsonian National Museum of Natural History collections growth, total and average from 1988 to 2000

	Acquisitions	Deaccessions	Net Difference 1988-2000
Totals	6,685,401	892,819	+ 5,630,262
Annual Averages	514,262	68,678	+ 469,189

Cataloguing is the creation of a full record, with descriptive detail, of all information about an object, assembly, or lot, cross-referenced to other records and files, and sometimes containing a photograph, sketch, film, sound, or other electronic data. Historically catalogue data were in the form of cards or sheets with more recent development of automated data. Material is catalogued when it has been examined by specialists and identified during a research project.

Inventorying is the creation of an itemized list of objects, assemblies, and lots that identifies each object's or lot's physical location. In 1970s and 80s NMNH concluded a total inventory (not counting each specimen, but accounting for all holding units such as drawers, jars, and cases) and a baseline was established. The NMNH has two basic types of inventory, cyclical and ongoing. On-going inventories are initiated in the departments, and are conducted as staff time becomes available in the course of other

collections related to specific curation projects, collections moves, databasing efforts, or specific research activity. Cyclical inventories allow for the overall analysis of the conditions and needs for maintaining the collections.

Deaccessioning is the removal of an accessioned object or group of objects from the museum's collection through a formal process. In 2003, NMNH deaccessioned a total of **11,414** specimens and objects in 68 transactions. Reasons for deaccesioning included collection refinement; damaged beyond use; distribution to other institutions following identification; exchange; scientific analysis; research; open exchange agreement with collegial institutions; per agreement with country of origin; repatriation; and return to owner.

Lending: NMNH maintains a very active lending program for research and exhibition purposes (Table 4).

Table 4. Smithsonian National Museum of Natural History collections number of outgoing and incoming loans in 2003 for different uses

2003 OUTGOING LOANS (LOANS)	# Transactions	# Items
TOTAL Loans Initiated:	**1,258**	**193,671**
For Exhibition	43	565
For Study	1,099	140,534
For Identification	36	46,008
For other purposes	80	6,564
FY03 INCOMING LOANS (BORROWS)	**# Transactions**	**# Items**
TOTAL Borrows Initiated:	**802**	**95,960**
For Exhibition	3	13
For Study	639	75,610
For Identification	140	19,165
For Accession Consideration	13	1,019
For other purposes	7	153

2.2.6 Changes in the museum's collections management system the past five years.

NMNH is implementing a commercial research collection information system (RCIS) to help manage its 125 million objects and specimens. NMNH has at this moment approximately 5.7 million **electronic** catalogue/inventory records. These electronic records document 22.9 million objects and specimens or **11.4 %** of the approximately 50 million records that will be required to adequately document the collections. Many of the older electronic records contain only basic information, and nearly all lack images. Collections information is widely distributed throughout NMNH's collecting units in non-automated records. NMNH plans to complete the migration of these records to the new RCIS in two years.

RCIS includes two major sub-systems: the **Multimedia Catalogue System** (MCS) text-based collections information with links to still images, video, and audio recordings. Second, the **Transaction Management System** (TM) that automates processes related to custody and legal ownership of collections. The TM assists in managing and tracking collections as they are acquired, loaned, borrowed from other institutions for research or exhibition, or permanently removed from museum custody by deaccessioning.

RCIS helps NMNH manage collections through desktop processing of transactions. Each year the museum acquires about 500,000 specimens, disposes of about 68,000, loans about 170,000, and borrows about 327,000. In 2002, these loans went to all US states and territories and over 100 foreign countries. Many of the specimens included in these transactions require filing permits with the US Fish and Wildlife Service and other agencies. Permits and other forms, reports, and letters are electronically generated through RCIS, resulting in much more efficient use of staff time.

RCIS will provide a central repository for many types of data, the most important of which are:

- specimen/sample level data (*e.g.,* catalogue and storage data, physical characteristics)
- collection event/locality data (date, site, geographical location, GIS referencing where available, ecological data from collection notes with look-up to geographical data)
- biological taxonomy data (the names themselves and their hierarchical relationships, synonymy)
- a thesaurus of culture, artefact, rock, mineral, and gem names (also with associated hierarchical relationships, synonymy)
- bibliographic and citation data
- research data (limited but with attributions for the persons who did the work)
- people and organizations data related to any of the above (*e.g.,* researchers, cataloguers, authors, collectors, identifiers).

2.2.7 A real life example

We will use Dr Terry Erwin's (1993) research in Ecuador as an example. Dr. Erwin is well known for his systematic and ecological research. His research has multiple goals, but his collecting methodology is designed to answer ecological questions regarding rain forest species diversity. Subsequently the same specimens are used in finer-grained taxonomic and systematic research.

By fogging the canopies of many tropical tree species with a biodegradable insecticide mist and analyzing the fallen specimens, he documented a vastly greater number of new species than anyone had ever expected. From the canopy of a single species of tree Erwin found more than 1,100 species of beetles. Given the specificity of beetle species on trees, and the number of tropical tree species, he extrapolated to conclude a global insect species diversity of 30 million. Dr Erwin's basic research on beetles has already multiplied by a factor of 20 accepted estimates of global species diversity[2].

In 1993 Dr. Erwin conducted 1,800 fogging events in tropical forests in Ecuador obtaining approximately 9 million specimens. These specimens continue to be used today for ongoing and new taxonomic and biodiversity research. The project trained Ecuadorian students to sort specimens by Class and Order and when possible by family and genus. All specimens were placed in jars containing "restriction labels" that refer to the Mutually Agreed Terms (MAT) between the Smithsonian and Ecuador. These labels accompany every loan of these specimens to scientists all around the world obligating those receiving the material to the conditions of the MAT. The restriction label moves from samples with multiple specimens to individual specimens as identification progresses.

Based on the mutually agreed terms , the Smithsonian returns 20 identified species per family to the Ecuadorian Politécnico University Museum to build their collection. Although The Smithsonian is willing to send more specimens to Ecuador, space and personnel capacities at the University limit the number of

specimens that can be stored and maintained there. The remainder stay at the Smithsonian or are transferred to other natural history collections to improve global reference collections. Nevertheless, the original terms and conditions accompany all specimens.

Scientists, who are usually world authorities on particular families or genera, further sort and identify the collection, often sending subsets of the original collection to even more specialized experts. Specimens are kept by experts for several years and eventually (often many years later), the material is returned to the Smithsonian. In taxonomy, identifications are done free of charge and frequently the only remuneration for the scientist is that they are allowed to keep 2-3 specimens (when possible) for their collections.

Proposed ABS rules could force museums to archive and review correspondence to reconstruct how many scientists in which countries examined the specimens; the costs of such work may far outweigh the benefits. In the single case of Dr. Erwin's Ecuadorian collections, specimens went to 20 scientists in 17 organizations/universities/museums in 4 countries over the last 21 years (Ecuador, Mexico, USA and Canada). Many, however, are still being used and identified as new research projects are started or new experts appear on the scientific scene. Indeed, the loaning and borrowing of these specimens will continue essentially forever as long as museums are willing to maintain these collections. Archival storage is essential to guarantee the value of these research specimens for future generations.

Finally, it may be decades or centuries before someone collects in that particular locality in Ecuador again—if ever. Given current trends, the habitat may be greatly altered before anyone can return. The original, serendipitous collection may then become the only available baseline data for that area to understand human-induced and natural changes.

2.2.8 The Importance of Natural History Collections

As discussed above, the natural history museum "collecting model" is nearly the opposite of the bioprospecting model where specimens are collected for immediate examination for traits useful for commercialization, answers of which are found in a relative short period of time. Basic questions in taxonomy, systematics, and ecology drive the collecting. Museums preserve collections in perpetuity, and from past experience we know that they will be used for analyses that we cannot now even envisage. Museum collections are constantly re-examined as new techniques and technologies of analysis develop revealing more and new information about nature and its processes.

One of the many ironies of contemporary biodiversity science and politics, is that due to the low funding for basic science around the world, museum scientists sometimes have to look for funding from sources that have other interests—such as commercially oriented enterprises. There are examples where this has been done successfully, such as in the ICBG (International Cooperative Biodiversity Groups) work. We know however of no researcher who cannot differentiate between the commercially oriented and the basic science applications that the material may be subjected to and field trips and work on the materials that are commercially oriented needs heightened scrutiny and clearly negotiated terms of benefit-sharing.

Material Transfer Agreements thus should recognize that museum collections are multi-purpose. These purposes include documentation of existence, taxonomy, systematics, natural history (life cycle, habits, habitats, specialized structures, evolution, etc), ecology, and, yes, bioprospecting and commercialization. However, the latter two are very minor elements in museum research and can be carefully delimited by rules consistent with CBD principles while still allowing the bulk of museum research and transactions to continue.

2.2.9 A practical approach to ABS negotiations

It is essential that CBD negotiators understand how taxonomy is done, by whom, where, and why and keep this in mind during their discussions. Museums are generally not for-profit enterprises; taxonomy *per se* generally generates no revenue. Increased transaction or accounting costs in taxonomic research,

whether from demands for non-monetary benefits (training, equipment, etc) or from additional paperwork and permits, cannot be passed on to consumers as they can by commercial bioprospecting companies. These costs come out of a relatively small, and if anything, decreasing resource pool. The net effect is that less taxonomic research gets done, the "taxonomic impediment" burgeons, suboptimal natural resource management decisions are made, money is wasted due to misidentification, and opportunities are lost. Taxonomy is basic to all research, conservation, and bioindustry; correct taxonomy benefits everyone. All developed countries and their museums have recognized the need for the sharing of non-monetary benefits, and indeed practiced this type of benefit-sharing well before the CBD and increasingly after its ratification. Major world museums are completely committed to training and institution building. They have worked together on programs such as the Global Biodiversity Information Facility (GBIF) to bring together the data in their systems and make it globally available.

To maximize taxonomic, training and other benefit sharing, transaction costs for access and the movement of specimens should be minimized.

2.2.10 Tractable national implementation

The importance of prior informed consent (PIC) or Mutually Agreed Terms (MAT) is not in dispute. However, the implementation of these concepts at the national level has not always been practical, transparent, easy or consistent. As an institution that transacts with most countries in the world, the Smithsonian must navigate the rules and regulations of each of these countries. PIC and MAT transverse multiple parts of every government's administration. It is naïve and simplistic to believe that the different concepts and implementation of rules undergirding PIC and MAT can be delegated to a single authority in most countries. These concepts minimally include research permits, collecting permits, export, and import permits. In most countries, different offices, even different Ministries, have the responsibilities for some or all of these permissions. Research on lands managed by local and indigenous communities, or on their biodiversity knowledge can require additional agreements (not formal permits, *per se*). A clear, transparent, low-cost process to obtain appropriate permits and to transact specimens in basic science research is required. Because the vast majority of collecting and specimen shipment is for basic research, most permits, certificates of transactions, and/or other documents apply to non-profit uses. Tracking these events falls to government agencies on the one hand, and museums and research centres on the other. Commercial organizations will ever only manage a small fraction of events. The costs of compliance will fall on those least able to afford it—governments of Megadiverse countries and non-profit museums and research organizations.

2.2.11 The ABS regime for basic science

Over the years of ABS discussion, it is becoming clear that there needs to be a dual track system: expedited transactions for basic science (regardless of its funding source) and higher scrutiny and obligations for applied and commercially oriented research. A generic Material Transfer Agreement (MTA) that allows for free movement of specimens for basic research is imperative for the survival of museums and non-commercial research. Clearly institutions that move material through an expedited process are under strong obligations and imperatives to make certain that material is not leaked into commercial uses. If it does, the trust which needs to undergird this system will be lost (or not gained) and the system will fall apart.

Natural history organizations need to be more proactive in revising their internal regulations and practices to make them clear, transparent, and consistent with CBD principles. The Royal Botanical Gardens at Kew spearheaded such a process for the botanical community, as have others for zoological and microbial communities, but best practices should be summarized and disseminated widely. Within North America, the Natural Science Collections Alliance has begun the process, and in Europe the Consortium of European Taxonomic Facilities (CETAF) is an appropriate vehicle. These and other similar organizations should collaborate and coordinate closely to move forward this program.

2.2.12 Disclosure of origin

Ongoing international ABS discussions provide nations of the world with an opportunity to negotiate rules and processes that protect their rights to fair and equitable sharing of benefits from the utilization of genetic resources. However, a narrow focus on the admittedly important area of disclosure of origin for patent applications and subsequent commercialization of genetic resources has inadvertently created a simplified and simplistic model of specimen use.

First, this simplistic model regards all collecting as commercially oriented. Second it assumes a short lag time between collecting, research, extraction, product development, and patenting of that specimen. While this model may fit a small amount of collecting targeted explicitly at bioprospecting, it does not fit basic taxonomic and systematic research, nor most ecological research or monitoring. It also does not reflect much of the plant and animal breeding research.

2.2.13 Closing the circle

Most new collecting of biological specimens today serves the basic sciences of taxonomy, systematics, natural history and ecology. Paradoxically, most of the discussion in the international community focuses on the small percentage intended or used for commercialization. This fundamental incongruity needs to be addressed as negotiations continue.

Understanding biodiversity, developing the fundamental information to support conservation, sustainable use, and equitably shared commercial benefits are all based on the non-sexy, non-profitable, yet fundamentally important basic sciences of taxonomy, systematics, natural history and ecology.

Perhaps we need to develop a principle of Taxonomists Rights, similar to Farmers Rights in the International Treaty on Plant Genetic Resources. Recognizing that taxonomy is based, just as traditional crop development, on principles and practice of access and exchange rather than exclusivity, the CBD could go far in addressing the current bottleneck on taxonomic research and beginning to free up capacity to overcome the taxonomic impediment, if the COP clearly reiterated its advice to Parties that access for taxonomy, systematics, natural history and ecology is needed for the success of the Convention.

2.3 The Royal Botanic Gardens, Kew: Herbarium and Millennium Seed Bank

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2.3.1 Introduction

The aim of this case study is to give an insight into the use of preserved and living plant material by a large collection of relevance to global biodiversity study, and to assess the practical implications of a system of certificates of origin. Our concerns are that any system should work to enhance scientific study and resultant benefit sharing. Care must be taken to ensure that the administration required to implement a system of certificates of origin is simple and does not draw resources away from the research and the fair and equitable sharing of benefits necessary for the conservation and sustainable use of biodiversity.

The Royal Botanic Gardens, Kew ("Kew") is a botanical garden and charitable trust whose mission is to ensure better management of the earth's environment by increasing knowledge and understanding of the plant and fungal kingdoms – the basis of life on earth. Kew is supported by the U.K. Department of Environment, Food and Rural Affairs (Defra) and receives grant-in-aid from Defra amounting to around 60% of its total income.

In pursuit of its not-for-profit mission, Kew works together with international partners to collect and curate plant material, to carry out scientific research projects to better understand and conserve plant biodiversity, and to exchange plant material with other research institutes for further non-commercial scientific study worldwide.

Kew employs some 550 staff, of whom some 60% are specialist plant and fungal scientists, curators and botanical horticulturalists. Among Kew's collections are 7.5 million pressed and dried herbarium specimens, 33,000 taxa of living plants, 750,000 fungal specimens and 10,000 taxa of banked seeds.

Kew has made clear its intention to honour the letter and spirit of the CBD, CITES, and other relevant laws concerning biodiversity. Kew has endorsed the Principles on Access to Genetic Resources and Benefit-Sharing (the "Principles"), which were developed in a project involving 28 botanic gardens from 21 countries worldwide, and cover the collection, acquisition and supply of genetic resources, and benefit-sharing. They provide the framework for Kew's partnerships and curatorial policy (www.kew.org/conservation/principles.html & Latorre García *et al.* 2001).

This case study focuses on two major Kew collections: the Herbarium and the Millennium Seed Bank ("MSB"). These collections have been highlighted since they relate to two very different types of biological material: preserved plant specimens and living germplasm. The practical systems in place at Kew to acquire, study, track and transfer these different types of material are distinct, reflecting the potential uses for such material and the corresponding level of 'risk'. Preserved plant specimens are very unlikely to be used for anything other than non-commercial research, but greater care is needed to curate living germplasm. Before any plans are laid to introduce a certificate system, it is vital to consider how collections are used, what benefits are generated and how such use and benefits would be affected by re-allocation of resources to administration.

2.3.2 Acquisition of Seeds and Herbarium Material by Kew

In accordance with the Principles and with best practice developed by Kew since the CBD came into force in 1993:

When acquiring plant material from *in situ* conditions, Kew works with in-country partners to obtain prior informed consent ("PIC") from the country of origin and any other relevant stakeholders, according to applicable laws and policies; and

When acquiring plant material from *ex situ* collections, Kew obtains PIC from the body governing the *ex situ* collection and any additional consents required by that body or the original terms of acquisition.

Each country has a distinct set of requirements in relation to the granting of PIC, which may vary depending on the type of material being sought, and the process of obtaining PIC is rarely transparent or quick. In some countries, it may be sufficient to obtain permits from the relevant government authority or landowner where any collecting activity is taking place; in other countries, it may be necessary to negotiate a complex legal agreement granting PIC to specified activities and subsequent uses by Kew.

During the first period of many of Kew's scientific projects, which are often funded by time-limited grants, much time is spent working out the legal and administrative requirements of a particular system, thus eating into time and money that might otherwise be spent carrying out valuable scientific and conservation related research. For instance, under Kew's Millennium Seed Bank Project, the average time taken to set up effective long-standing scientific partnerships is around 19 months, before project activities begin. Much of that time is spent identifying the correct authority(ies) to grant written PIC in accordance with relevant national laws, on drafting and negotiating appropriate written agreements and on actually signing off the relevant paperwork. The process has been complicated by the fact that, since the advent of the CBD, many countries of origin have been in a state of legislative flux and unable to unable to move fast (or in some cases, at all) without authority at the highest level in government. Kew would be extremely concerned at the introduction of any system of certification that added to the already complex process of obtaining PIC for scientific research.

2.3.2.1 Acquisition - Herbarium Material

Kew currently receives about 2,500 specimens each year through *in situ* field collection by Kew staff in collaboration with international botanical partners in the country of origin in accordance with national permitting laws and regulations and any applicable Memorandum of Understanding.

The majority of herbarium specimens accessioned into the Kew collections are received from other sources, mainly botanical gardens and university departments whose main goals are non-commercial scientific and conservation research. In 2001-2003, Kew accessioned around 23,000 specimens per year from other collections. The majority of material received is not specifically solicited by Kew. Institutions sending material to Kew do so as part of their research programmes, for example, they may require their material to be named using Kew's existing collections and library. One-off donors of material (as opposed to regular institutional exchange partners) are asked to sign a donations letter to clarify that the material was obtained legally and may be used under Kew's standard terms.

All herbarium material is accepted by Kew on the basis that it can be used by Kew for scientific, education and conservation related work, that it can be loaned to other research institutions for similar non-commercial research work and that it has been collected in accordance with all applicable laws and regulations in force at the time of collection. Taxonomic determinations, research results and associated publications are routinely shared with colleagues in the countries of origin and Kew also undertakes a significant amount of taxonomic and conservation related training and education with partners.

Each specimen arrives with a label (unless labels are produced later from field notebook entries) bearing baseline information such as: collector name; collector number (each specimen has a different number, in a sequence); date; provisional taxonomic name; country; state and district; locality; location (grid reference or latitude and longitude, increasingly obtained using GPS); description of vegetation, topography and soil types; description of the living specimen (sometimes lengthy). The collector's number, and sometimes name, is generally attached to each specimen at the time of field collection

(written in pencil on a small piece of card, tied on by string), so that if a label goes amiss, the specimen can still be linked to its data. A specimen without data is worthless to a collection.

Kew staff generally produce labels for the specimens they have collected using a database (depending on the project logistics, databasing may occur while still overseas or back at Kew), although this is a relatively recent development. Collections around the world provide labels that are produced in differing ways; an increasing number send specimens with database-produced labels, very occasionally with a barcode attached, but it is still the case that most *ex situ* collections use different and often incompatible database systems, so specimen data is rarely transferred electronically from one institution to another (thus preventing the need for new databasing).

Kew does not have sufficient resources to database label data for each individual specimen entering and leaving the herbarium; effort and resources are focussed on databasing individual specimens linked to current research and data-sharing projects and type specimens sent on loan. Instead, incoming and outgoing herbarium specimens are databased on a batch basis (a bundle of specimens received from an institution is given one number). The batch number becomes obsolete after the material is incorporated into the collection. Any special terms of acquisition are transferred onto the herbarium labels. However, in practice Kew rarely accepts herbarium material with unusual or very restrictive terms. This is due to the practical difficulties of implementing special curation requirements and the potentially lessened utility of such specimens to science.

2.3.2.2 Acquisition - Millennium Seed Bank

In 2003, around 2,000 seed collections were accessioned into the MSB. The majority of these were sent to Kew from international partners. These partnerships are based on legally binding Access and Benefit-Sharing Agreements ("ABSAs") setting out the precise terms on which PIC has been granted, how the seed may be acquired and used, and all agreed benefit-sharing activities (Cheyne 2004).

The remainder of collections were donated to Kew as part of an on-going donations programme with particular partner countries and institutes. Donors are asked to sign a donations letter to clarify that the material was obtained legally and the ways in which the collection may be used.

As with herbarium acquisitions, the fundamental basis on which material is accessioned into the MSB is that the material can be used by Kew for scientific, education and conservation related work and that it has been collected in accordance with all applicable laws and regulations in force at the time of collection. Benefit-sharing may include the sharing of research results and associated publications, the transfer of know how and technology to facilitate the development of seed banking facilities in the country of origin, and significant opportunities for relevant training and education both in the country of origin and in the United Kingdom.

All seed collections are accessioned individually (sample by sample) onto a specific Seed Bank Database, which contains basic information on terms of acquisition together with field data and laboratory-based processing and germination testing results and any supply to third parties. All collections are labelled with a unique serial number which links the collection to the record details on the Database. This database makes it possible to track collections from country of origin to supply to third parties. The ABSAs vary on the terms under which collections may or may not be used and passed on to third parties, and the database means it is possible to curate the collections accordingly.

2.3.3 Use of Herbarium and Seed Specimens at Kew

Material in Kew's collections is available for use by Kew staff and authorised visitors for scientific, education and conservation research purposes only, and in a manner consistent with the terms on which it was acquired by Kew. Any special conditions prohibiting particular uses are indicated on labels and/or database fields, which staff and visitors must check before using. When any material is sampled or transferred within Kew, baseline data and any special terms of acquisition and use are also transferred to

the applicable departmental database. In the very unlikely instance that any potential commercial use was envisaged, Kew would contact the country of origin to seek new prior informed consent for this use and negotiate a separate agreement.

2.3.3.1 Use of Herbarium Material

Herbarium specimens are most often used for taxonomic, evolutionary and conservation-focused research. This usually involves study of gross morphology, phenology and geographical distribution by staff and visitors, or more rarely, more detailed study such as anatomical studies or sampling for DNA analysis. If any material is removed from a herbarium sheet, a note is physically added to the specimen. It is not practical or feasible to produce regular reports of how individual herbarium specimens are used at Kew, to keep track of such reports and link them back to individual specimens. Recording the use of a herbarium specimen would take as much or more time as actually consulting it in the majority of cases. Thus monitoring use would dramatically reduce the amount of research carried out on specimens and consequently greatly diminish the benefits to conservation. Instead, Kew places emphasis on training staff to carry out projects based on strong partnerships which will facilitate targeted benefit-sharing and capacity building and long-term collaborations.

2.3.3.2 Use of Seeds

Seeds in the MSB collections may be used by Kew for seed studies including post-harvest seed handling, germination tests, moisture relation tests, seed dormancy research and diagnostic characterisation, or may be grown up to produce voucher herbarium specimens for taxonomic identification or to be displayed to the public. The use of collections for these purposes is recorded on the Seed Bank Database, and all use of the MSB seed collections is regulated by the curation staff thereby limiting risk of breach of ABSA terms.

2.3.4 Transfer of Herbarium and Seed Specimens by Kew

Kew may transfer plant material on terms that are consistent with the terms on which it was acquired by Kew.

2.3.4.1 Transfer of Herbarium Material

Kew frequently loans herbarium specimens to other research institutions such as herbaria and universities whose main goals are conservation and scientific research. In 2001-2003, Kew loaned 11,000 specimens per year. All loans are made on standard written terms that prohibit any commercial use of the material loaned and any sampling from the specimen.

In common with other collections of herbarium material and in order to facilitate taxonomic research and to insure against damage to the collections, Kew frequently exchanges duplicate herbarium material with other herbaria. In 2001-2003, Kew distributed around 18,000 duplicate herbarium specimens per year. Kew also supplies samples of specimens to researchers in herbaria and universities on request, where allowed by the terms of use; around 1550 samples per year were supplied in the same time period. All supplies are made under standard written material supply agreements which state that the material shall only be used for non-commercial scientific purposes and prohibit any commercial use of the material supplied or its derivatives. Transfer to third parties is allowed if it is under terms consistent with the original terms of supply.

2.3.4.2 Transfer of Seeds

Seed collections are not loaned. However, the MSB, like other botanical and scientific institutions does maintain a seed list which sets out the details of those collections from which sub-samples may be supplied (in accordance with ABSAs) to other research institutions for non-commercial research or other use such as reintroduction. In 2003, Kew supplied around 600 seed samples (each containing 50 seeds). All supplies are made on standard written material supply agreements that state that the material shall only be used for non-commercial scientific purposes and prohibit any commercial use of the material

supplied, or its progeny or derivatives. Transfer to third parties is allowed if it is under terms consistent with the original terms of supply and Kew is notified of the transfer.

2.3.5 Estimating costs to Kew of a Certification of Origin

The potential impact of a certificate system is difficult to gauge, and depends in part on whether a certificate would be required at the original point of access, or only at the time when the genetic material is exploited for commercial purposes and when intellectual property is applied for or is acquired.

At the stage of acquiring a certificate of origin at point(s) of access, Kew would be extremely concerned about the introduction of a system that would add to the already considerable challenge of obtaining PIC for scientific and conservation related work. There could be wide variation between countries in how efficiently any process operated, and it would likely involve a more complex process than current permit systems. Kew staff currently invests considerable time, and funds, seeking appropriate PIC at national and local levels before beginning work. Very few botanical institutions have the resources to spend well over a year (as identified by the Kew Millennium Seed Bank project) in clarifying the legal and administrative requirements of scientific collaboration in a post-CBD world. The risk of added uncertainty and delay could lead to a greatly reduced amount of international collaborative research.

It is somewhat simpler to estimate some of the additional costs for institutional acquisition and exchange. Kew has calculated that it carries out a total of approximately 53,000 transactions concerning herbarium specimens per year. On the assumption that a certificate system would involve the databasing of all incoming and outgoing individual specimens and associated data and linkage with a certificate number, Kew would need to hire at minimum 6 additional staff purely for data capture of new Herbarium accessions, loans and transfers. Additional staff resources would be needed at varying levels of authority and salary to manage databasing staff, manage and chase documentation, manage archives, administer additional IT system requirements, maintain data quality control, and design and refine implementation systems. This would involve creating at the very least another 3.5 staff posts, as well as significant overheads associated with information storage and retrieval, and staff needs. Far more staff would need to be employed if it was necessary to record every time a specimen was consulted at Kew.

The increase in resources needed simply to manage and implement the system would greatly reduce the resources available for use of the collections in conservation. As virtually none of the material concerned is commercialised, no commercial benefits would be produced downstream to justify the expense, and far fewer non-monetary benefits would result. Such a system would not even serve to facilitate benefit-sharing. The benefits that arise from Herbarium research are generally not traceable to the use of individual specimens, but rather to broad comparative use of hundreds or thousands of specimens, resulting in conservation and biodiversity research tools such as floras, identification guides, Red Data lists, vegetation maps and evolutionary studies. A certificate system that did not necessitate individual specimen coding or databasing or updating with institutional information would be less damaging to research activity.

The above estimates assume a certificate system that would create a unique number that could be added to relevant database fields and labels. For the MSB, where all material is databased, the administrative impact of such a system would be relatively smaller than for the Herbarium. However, a further complication would arise if the transfer or sub-samples of collections to third parties should require the creation of different certificate numbers from the original collection; this could necessitate another 0.5 staff post.

For both the Herbarium and the MSB, a certificate system relying on the circulation of actual hard copy certificates would lead to much higher staff and resource costs and time delays, if institutions had to distribute, store, reproduce or request copies of hard copy certificates, rather than record a number in database fields.

This case study only addresses the some of the potential impacts of a certificate system on the relatively static Herbarium and MSB collections at Kew, not the potential logistical complications and costs arising from application to the living, breeding, sometimes cross-pollinating plants in the greenhouses and grounds. The acquisition and supply of living material in the gardens is monitored in a specimen-level manner similar to the MSB example. However, the material is handled by a wider range of staff, on display to a large visiting public and subject to natural processes such as those noted above which are impossible to document.

2.3.6 Conclusion

Finding out about and obtaining PIC for basic biodiversity research such as is carried out by Kew is already a complex, resource-intensive and lengthy process. Any system that added to this process could be extremely onerous for botanical institutions, where the main purpose underlying access is non-commercial scientific research, education or conservation, not commercial use. Further, the costs of implementing the degree of change suggested by a certificate system are likely to be at the direct expense of basic biodiversity research. Indeed, a certificate system could lead to a large decrease in collection and exchange of scientific material. This in turn would lead to in-country institutions gaining fewer authoritative names on specimens from experts in the global scientific community, weakened capacity to conduct biodiversity inventories, and fewer opportunities for biologists to pursue research at regional or global levels, at a time when such studies are proving increasingly invaluable for targeting of conservation efforts. A reduced flow of seed material would lead to a reduction in collaborative research on seed banking needs across the vast range of wild plant species, meaning a reduction in the efficient banking and use of seed collections, and in some cases the potential extinction of un-banked species. A system that concentrated on tracking material for which commercial use is intended or likely would be a more meaningful and effective use of resources.

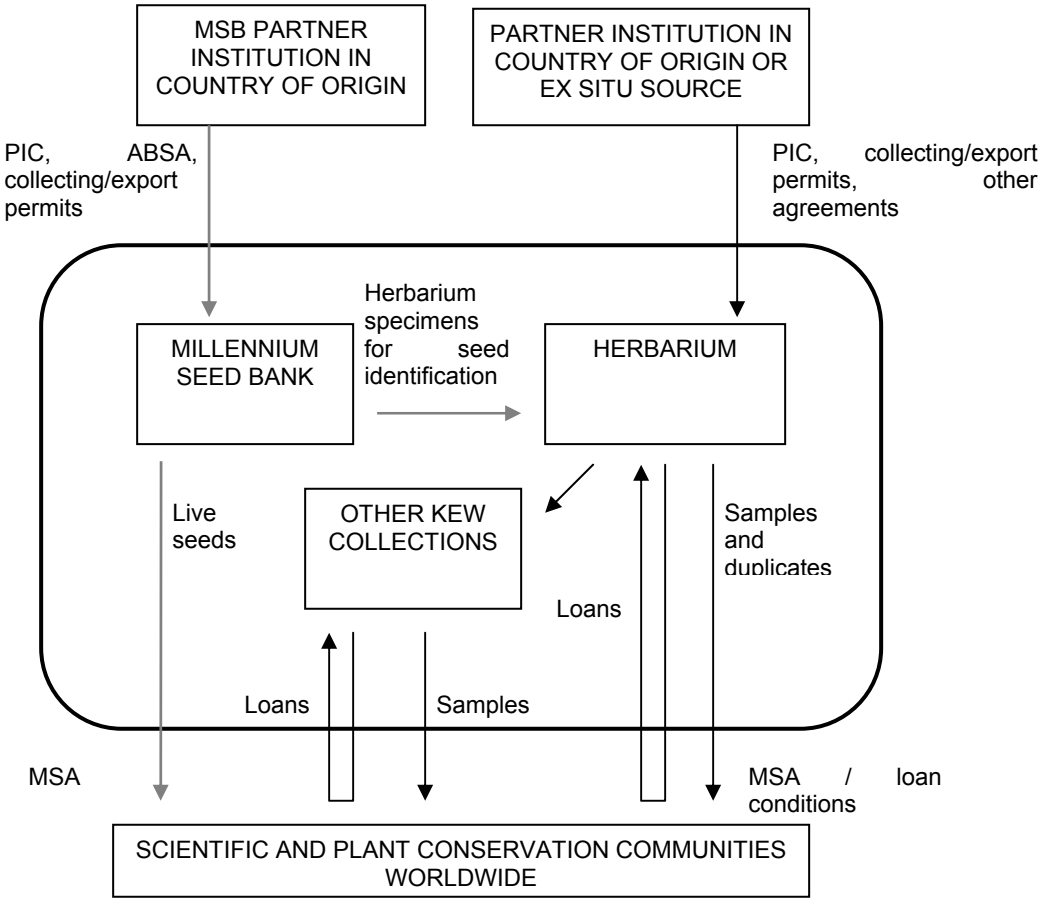

Figure 2. Flow diagram for material entering and leaving the Millennium Seed Bank (MSB) (grey arrows) and Kew Herbarium (black arrows). Further use and transfer of material provided to the MSB depends on the terms of each MSB access and benefit sharing agreement (ABSA). All material supply agreements (MSAs) and loan conditions illustrated stipulate non-commercial uses.

2.4 Microbial biological resource centres: An overview

David Cunningham

2.4.1 Microbial genetic resources

Microbial resources encompass a range of life forms from bacteria, plasmids and viruses to microscopic fungi. Broader definitions of the term encompass human, animal, vegetable and non-specific tumour cell lines; and nucleic acids, DNA banks, clone lines and DNA and RNA databases. Only a small proportion of microbes have been described, for example most estimates are that less than 1% of over 3 million bacterial species have been isolated and identified.

Most developed countries and a few developing countries maintain national collections of micro-organisms as an essential infrastructure requirement for science and industry. 483 culture collections in 65 countries are registered in the World Data Centre for Microorganisms (WDCM). Together, these collections maintain over 1.1 million microbial cultures including around 11,000 species or sub-species of bacteria (445,000 cultures), 20,000 species or sub-species of fungi (375,000 cultures) 10,000 virus collections, 10,000 cell lines and 277,000 other 'microbes' (Bailey 2001; Sugawara 2004).

This case study is based on visits to three microbial collections, published literature and interviews with a number of microbiologists at the 10th International Congress for Culture Collections, which was held in Tsukuba, Japan, in October 2004.

Microorganisms are a source of many pharmaceutical compounds such as vaccines, antimicrobial agents, antihelminthics, antitumour agents, insecticides, immunosuppressants, immunomodulators and vitamins worth around USD$35 to 50 billion per year in the 1990s (CME 1995). Microorganisms are also used for many processes in the food industry, for example in baking and the manufacture of wine, beer, fermented feeds and foods. In agriculture they are used to inoculate crops and as organic fertilizers as well as in pest control. Genetic elements taken from microorganisms are used in the development of transgenic plants resistant to pests, herbicides and diseases, e.g. genes of *Bacillus thuringiensis* transferred to crops making them insect resistant. Standard strains of microbes are used in aseptic tests and for determining antimicrobial activity of new antibiotics.

Microbes also have applications in other industries such as mining and environmental remediation. Since little is known of most microbes they are considered a practically untapped resource that could be harnessed and enriched for many more applications in medicine, bioremediation, improvement of food and feed nutritive value, and other agricultural and industrial uses. For these reasons, many companies and microbial collections are actively involved in screening for novel compounds of potential commercial value to a range of industry sectors. However, the vast majority of microbial collections are maintained for basic science and teaching purposes.

The CBD now provides a framework for international partnerships to exploit microbial resources. An example is a joint venture agreement between the Forest Research Institute of Malaysia (FRIM) and Nimura Genetic Solutions (NGS) from Japan. This agreement covers screening tropical rainforest soil microorganisms for bioactive compounds from 2002 to 2007. Most of the research and development activities (isolation, identification, characterisation, fermentation, extraction and analysis) are conducted in Malaysia. The agreement includes technology transfer, training, joint IP and patent ownership and profit sharing on products developed through milestone payments and royalties. A separate Material Transfer Agreement facilitates the movement of biological materials between the countries (Krishnapillay *et al.* 2004, Deki 2004).

2.4.2 Supply chain arrangements for microbial genetic resources

Since microorganisms are ubiquitous in nature they can be collected from almost anywhere. Some research is focussed on particular ecological niches such as thermal vents or symbiotic relationships with

plants and animals. This strategy is particularly important for commercial users because products of microbes such as enzymes need to function in a range of temperatures and pH conditions in industrial processes.

Microbial collections may undertake their own collecting expeditions, sometimes in partnership with a local collaborator, or receive material from researchers in academic and industrial sectors. Material is often extracted from soil samples containing unknowable numbers of individual organisms of 100 or more species and enters the collection as an actively growing culture of a single species which the collection stores in ampoules.

Microbial resource collections typically deal with two kinds of material, deposits for accession to the collection and material sent for identification which is not a deposit unless there is a request to add the material to the collection. Some collections offer a 'safe deposit' category for material that is not publicly accessible, for example a backup of cultures used by a company for industrial fermentation in wine or cheese making. Some collections handle a fourth category, deposits to an international depositary authority (IDA) under the Budapest Treaty for patent purposes.

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure came into force in 1980 and has 59 member countries. When a patent application involves the use of a microorganism, the microorganism should be deposited at one of the 35 International Depositary Authorities (IDAs) in order to allow the reworkability of the invention. The regulations of the treaty describe the procedures that depositors and depositary authorities must follow. A Code of Practice was developed by several IDAs to harmonize the procedures applied in support of the intent of the Budapest Treaty (Bosschaerts 1998; BCCM 1998; Weihs 2004).

One of the main roles of microbial collections is fundamental research on microbial taxonomy. The output is measured in terms of validly published families, genera and species of microbes. Description of a new species requires deposit of a living type culture and a journal paper referring to the type specimen by an accession number which also identifies the collection where the culture is maintained. Bailey (2001) estimates that less than 10% of cultures in DSMZ (Germany) are of economic interest, and this figure is probably representative of most public collections.

Microbial collections can enter into agreements for access to microbial collections that include potential commercial uses. For example, NITE[16], a non-profit research organization in Japan can enter into agreements with foreign countries to utilise microbial genetic resources and ensure that any benefits are shared. In 2002, a Memorandum of Understanding (MoU) was concluded with Indonesia's Agency for the Assessment and Application of Technology (BPPT). In 2003, the first Project Agreement under the MoU was established with research groups from the Indonesian Institute of Sciences (LIPI) and other Indonesian organisations. Under this agreement, transfer of genetic resources from Indonesia to Japan is based on Material Transfer Agreements (MTAs). The first stage of a project is taxonomic and ecological studies of microorganisms in Indonesia. The second and third stages will involve basic research and consultation with the private sector on potential industrial applications. To date, the benefits have been non-monetary in the form of training provided to Indonesian researchers (NITE 2003; Sumida 2004; Ando *et al.* 2004).

Private companies also access microbial resources and are increasingly aware of the requirements of the CBD and other international agreements. Novozymes A/S, a Danish company that produces industrial enzymes has established a biodiversity research collaboration with BIOTEC[17], a research organization in Thailand. Under this agreement, Novozymes pays for the option to screen many strains for potentially useful products and also agrees to share royalties on any actual products that may arise in future. The

[16] National Institute of Technology and Evaluation, Department of Biotechnology (Japan).
[17] National Centre for Genetic Engineering and Biotechnology (Thailand).

initial isolation and screening is undertaken in Thailand with technology transfer support from Novozymes. The focus of Novozymes research is on products with no traditional knowledge input because of uncertainty in handling TK under international agreements (Lange 2004).

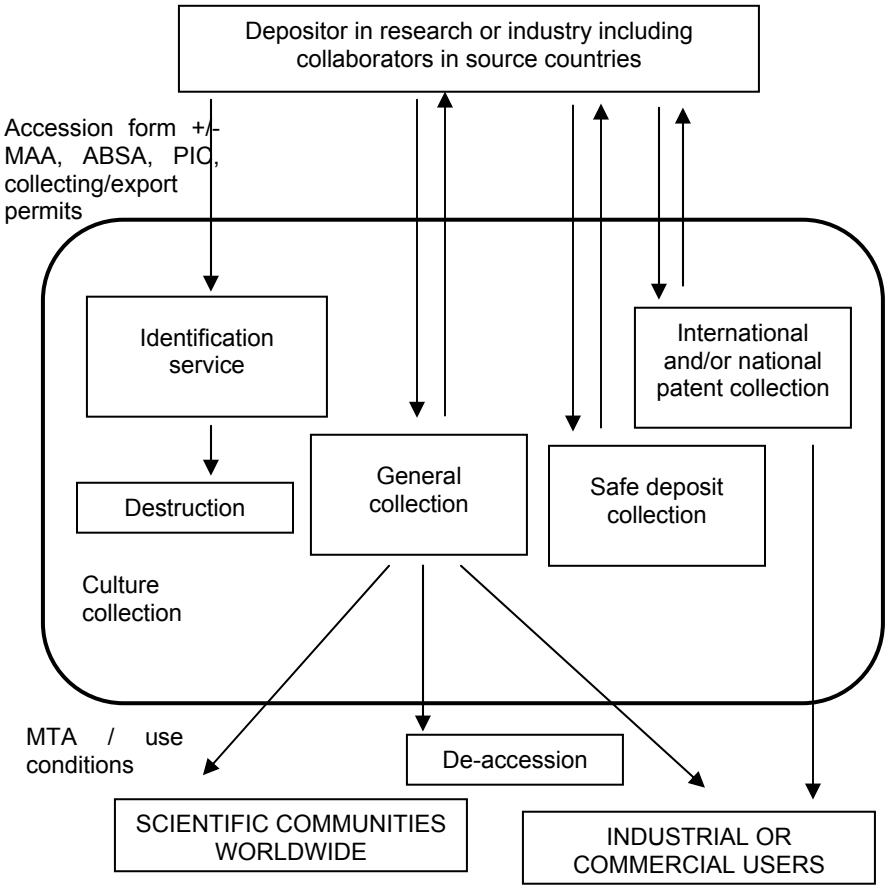

Figure 3. Generalised flow diagram for material entering and leaving a range of microbial collections.

2.4.3 Documentation and mechanisms to track microbial resources

2.4.3.1 Accession

When most collections receive material, it is usually accompanied by an accession form or Material Acquisition Agreement (MAA) listing information on the material. Tracking and identification of microbial material typically involves assignment of a unique accession number to each strain that is added to the collection. Under the NITE-Indonesia project, each sample collected has a reference number and each microbe that is identified is assigned a serial number which is linked to the sample number and these lists of information are shared with the provider country.

For most pre-CBD holdings in large collections, data on the country of origin ranges from sparse to comprehensive (WFCC 1999). Post-CBD, many collections formalised the requirement that the country of origin or a more precise geographical location of the source of the organisms be specified by depositors. Others also began requesting other information demonstrating compliance with the CBD and legal rights

to the material. For example, some accession forms now request that depositors provide information on the history of each specimen including details of any intermediaries (e.g. ATCC[18] 2001). Others go further and also require details of the competent authority that issued PIC for sampling the material (e.g. CABI[19]) while others record all these details as well as any benefit sharing agreements between any parties involved (e.g. DSMZ [20] 2003). In practice however, many collections still receive no documentation on PIC or MAT with the majority of cultures they receive.

2.4.3.2 Internal transfers

Microbes can be stored alive for decades under a range of storage conditions that most commonly include freezing at minus 80 degrees Celsius, liquid nitrogen freezing and freeze-drying. Cultures are multiplicated to prepare copies for external transfers while retaining the original strain. Tracking of cultures internally is done by reference to the unique accession number assigned to each culture.

2.4.3.3 External transfers

While a range of accession forms are used to cover different biological materials (e.g. bacteria, yeasts and filamentous fungi) collections often use only one type of transfer agreement since biological differences are not relevant to the terms and conditions of transfer. For example RIKEN[21] has three separate accession forms but only one order form for cultures (available online at www.jcm.riken.jp). Transfer agreements may be in the form of MTAs although many collections do not apply any restrictions to the use of material (e.g. NRRL[22]).

Cultures are usually packed with shipping documents including an invoice and safety information. Different rules for shipping cultures apply to different risk groups or levels of pathogenicity. Microbial cultures may also be de-accessioned from a general collection, i.e. destroyed if the collection cannot justify the cost of maintaining the culture. Budapest Treaty deposits must be stored for at least 30 years, irrespective of whether the strains are used for patent applications or not while safe deposits can only be terminated by the depositor.

2.4.4 Costs of tracking microbial resources

Microbial collections handle thousands of transactions per year. For example, NRRL distributes 4,000 subcultures per year and acquires 1,000 to 2,000 new accessions per year to its collection of around 85,000 cultures. IFO[23] maintains around 18,000 strains and distributes around 8,000 samples per year (Bailey 2001).

Many collections publish catalogues listing all of the strains they maintain, historically these were published as books but in recent years online catalogues are increasingly common. Of the 483 collections registered in the WDCM, 113 produce catalogues of their holdings which can be accessed on-line (Bailey 2001).

Online catalogues can be linked directly to the collection's database, for example at IFO (Bailey 2001) and FIRDI (Chang *et al.* 2004). FIRDI has established an Oracle database and used JSP to develop a web interface for internal and external use. All information on biological materials is integrated into this database including its background, experimental results and stock data. A workflow system tracks resources entering and leaving the collection using standardized electronic forms. Staff can access all information while restricted access is available to the public through the internet.

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[18] The American Type Culture Collection (USA).
[19] CABI Bioscience UK Centre (Egham) Genetic Resource Collection.
[20] Deutsche Sammlung von Mikroorganism und Zellkulturen GmbH (Germany)
[21] Japan Collection of Microorganisms (RIKEN) (Japan).
[22] The Agricultural Research Service Culture Collection (USA).
[23] The Institute for Fermentation (Japan).

The Common Access to Biological Resources and Information (CABRI) is a European network linking 21 microbial collections in a database that can be accessed online. Individual collections maintain their own databases but by adopting common specifications users can search all of them simultaneously and order materials through a common gateway (OECD 2001; www.cabri.org).

2.4.4.1 Material entering collections

The cost of accession of a bacterial culture is estimated at US$2,500 to 3,000 at DSMZ and accession of different items to ATCC costs from US$5,000 to 10,000. These costs include quality control, validation, long-term preservation and global distribution (OECD 2001). The proportions of these costs which are due to entering data are difficult to estimate and have not been reported.

Most collections operate on a not-for-profit basis; some have a policy of cost recovery for provision of cultures for research purposes. Public funding for collections ranges from a small fraction to almost 100%. The ATCC receives only 9% of its funding from government and generates the rest from culture fees and services. While no charge is levied for accession of cultures to ATCC, a market-oriented fee schedule applies to distribution of materials. In contrast, CBS[24] calculates the service charge for distribution on the basis of actual costs to prepare and maintain the sample, but not to maintain the culture it was prepared from (Bailey 2001).

2.4.4.2 Material leaving collections

Collections do not typically monitor compliance with MTAs. In the case of patent deposits, the patent owner may be informed of the details of the authorised persons acquiring the patented strain but the collection itself does not monitor use of the culture. One collection visited experimented with monitoring use of their material by 3rd parties through tracking the accession number which scientific journals require to be published with research on microorganisms. Novozymes reports the country of origin in any publications and patent applications under the company's voluntary code of conduct (Lange 2004).

The taxonomic community requires identified species to be deposited in two or more countries for distribution without restriction hence most collections request that depositors assign the right to the collection to make the material freely available. For example, one journal requires that "Type strains of culturable species must be deposited in at least two or more public culture collections from two or more countries and accession numbers must be provided" (IJSEM 2004). Some researchers identify a problem with MTAs that restrict distribution because this conflicts with the taxonomic practice of making type specimens freely available from culture collections in two or more countries.

2.4.5 Conclusions: practical aspects of tracking microbial resources

Accession practices vary between microbial collections. A range of information is required for the deposit of a new strain or to accompany microbial resources that are provided to other collections or researchers. In most cases, this information is databased either partially or fully. If material were provided under a certificate of origin number, there would be little incremental cost in entering this number and associating it with the culture or the existing accession number of the culture and subcultures subsequently provided to third parties.

For microbial collections with comprehensive CBD policies and adequate computer resources adoption of a certificate of origin number would not be problematic or expensive. In cases where a collection lacks IT infrastructure, accession processes could involve transcription of a certificate of origin number to the index card for each accession and transcription again to each despatch. Without a database it would be difficult to extract a list of all accessions under one certificate number.

Some experts note that it is easier to falsify the source of micro-organisms than plants or animals because microorganisms can exist in very small environmental niches in many countries whereas plants and

[24] Centraalbureau voor Schimmelcultures (The Netherlands)

animals generally require larger habitats which may be identified with a specific location, e.g. rainforest. Users sometimes cannot say with certainty the country of origin, only the source. For these reasons, a compulsory declaration of origin or certificate of origin scheme is seen by some as unworkable for microbiology. Laird and ten Kate (2001) discuss differences between tracking microbes and other biological resources noting that microbes can be collected with minimal infrastructure or local collaboration and are easily packed and shipped. They reported that some companies still asked employees to collect soil samples from other countries when on holiday, for the purpose of investigating microbes from the soil. It is unlikely that many companies would still do this however it is reportedly not uncommon among research academics.

2.5 INBio: Tracking genetic resources of Costa Rica

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2.5.1 Bioprospecting and biodiversity research at INBio

Costa Rica's National Biodiversity Institute (INBio) was created in 1989 as a non-governmental, non-profit association for private founding members and it has been declared a public good. Its mission is to promote a new awareness of the value of biodiversity, and thereby achieve its conservation and use it to improve the quality of life. INBio has two Units or Departments of relevance in terms of transfer and tracking of biological materials, 'Bioprospecting' and 'Inventory'.

2.5.1.1 Bioprospecting

In 1991, INBio developed the concept and practice of 'bioprospecting' as one of the answers to the need to use, in a sustainable way, Costa Rican biodiversity to benefit society. This concept continues to gain acceptance in government, scientific, academic and managerial circles. It refers to the systematic search of new sources of chemical compounds, genes, proteins, microorganisms and other products that possess a current economic value or potential and can be found in our natural biological wealth. The use of biodiversity presents opportunities and challenges to promote and organize infrastructure investments and human resources that add value and contribute to its conservation. Bioprospecting involves the transfer of biological specimens including samples, fractions or extracts of interest according to the specific collaboration in place with private companies, scientific institutions and universities.

2.5.1.2 Biodiversity inventory

The Inventory Unit conducts basic taxonomic research with around 200 collaborators around the world and this by necessity involves transfer of specimens to other countries. So far, the inventory has focussed on five groups namely arthropods, nematodes, marine molluscs, fungi and plants (INBio 2004). Around 3 million specimens have been collected to date and are mostly stored dried or in alcohol.

2.5.2 Supply chain arrangements for INBio's genetic resources

INBio has a formal agreement with the Ministry of the Environment and Energy (MEE), which allows it to carry out specific activities relating to the inventory and use of biodiversity in the government's protected areas. Under that agreement INBio actively develops biodiversity prospecting in the protected wild areas of the country, with the participation of the national and international academic and private sector. Research is carried out in collaboration with investigation centres, universities and national and international private companies, by means of investigation agreements that include key elements, such as:

- Access (limited in time and quantity);
- Equity and compensation
    - Research budget
    - Benefit sharing (which may include royalties and milestone payments)
    - Technology Transfer
    - Training;
- Non-destructive activities; and
- Up front payments for conservation.

The agreements specify that 10% of the research budgets and 50% of the future royalties be donated to the Ministry of the Environment and Energy (MEE) to be reinvested in conservation. The research budget supports the scientific infrastructure in the country, as well as activities of added value aimed at conservation and sustainable use of the biodiversity. Up to now, no product has reached the market and no royalties have been paid but there are some products under development, especially related to

ornamental and herbal products. Tamayo and Gamez (2003) report that 27 patents have been filed under the commercial agreement with Merck. Royalties and milestone payments under INBio's agreements will be shared 50:50 with the Ministry of the Environment. Although there have been no royalties to date; these agreements and other contractual relationships have provided great benefits to Costa Rica including:

- Monetary benefits through direct payments;
- Payment for supplied samples;
- Funding for research budgets;
- Transfer of important technology which has enabled the development of the infrastructure at the Institute (biotechnology lab, etc.), which can be used for the investigation and generation of its own products;
- Training of the scientists and experts in state-of-the-art technology;
- Negotiation experience and knowledge of the market and the probabilities of searching for intellectual uses for biodiversity resources;
- Supporting of conservation through payments made to the Ministry of the Environment for the strengthening of the National System of Conservation Areas;
- Transfer of equipment to other institutions, such as to the University of Costa Rica; and
- Establishment of national capabilities for assessing the value of biodiversity resources.

INBio's bioprospecting partners include or have included Merck, National Institute of Health (USA), Givaudan-Roure, British technology Group (BTG), Diversa, INDENA, Phytera, Eli Lilly and Akkadix as well as the Universities of Strathclyde, Massachussets and Guelph. The uses of material that have been explored include research and development activities which range from pharmaceuticals to agricultural and industrial chemicals. These agreements are well documented elsewhere and will not be detailed in this case study which focuses on tracking and tracing of resources in general terms.

2.5.3 Documentation and mechanisms to track microbial resources

2.5.3.1 Accession and internal transfers

Material is collected in the field under a permit system with separate permits for export and domestic use. A standard agreement applies to taxonomic research while unique legal agreements are developed for bioprospecting research.

Specimens are often only identified to Family or Genus level in the field and so many specimens from a collection trip may have the same textual description on the label. This can be a unique collecting number for each specimen, the name of the collector, the date and information about the location. As specimens are sorted in the laboratory, each receives a unique barcode which is physically attached to the specimen e.g. pinned to an insect or fixed to a vial of fungi.

All the information subsequently generated on a specimen is registered in a database with reference to the barcode number. Basic information includes collection data (where, when, methods etc), taxonomy, biology, history and SIG. All transactions are recorded including the loans and transfers of material and details of the researcher, objectives of the project, dates and list of materials.

The Institute's database (ATTA) is based on Oracle with a Powerbuilder interface. Separate databases store publicly available information on specimens and restricted information which includes documentation such as MTAs.

2.5.3.2 External transfers for bioprospecting

All material leaving INBio's Bioprospecting Unit is labelled with a barcode and identification number. INBio uses legal and contractual mechanisms for the tracking of the Genetic Resources as follows:

1. Access is limited in time and quantity. Any transfer to a third party of sample is made using a material transfer agreement (MTA) or under a collaborative research agreement (with companies, research

institutions, etc). INBio agrees to transfer the materials specified in detail in the annex of the specific MTA or contract.

2. The recipient may transfer the material to third parties only with prior written authorization. The terms and conditions of the original MTA shall apply equally to these third parties. A letter with the following wording is usually required to accompany all transfers:

> "This material has been received under a Material Transfer Agreement which includes terms and conditions for use by Third Parties".

3. The Recipient shall assign a unique identification number to each of the materials obtained and to the resulting materials from the research that will ensure traceability.

4. Usually the recipient is obligated by the contract to maintain complete and accurate internal written records and reporting systems so as to keep track of all the materials and any research and/or development activities.

5. The recipient has the duty to allow INBio upon request to audit and/or inspect such records and reporting systems from time to time and to make such changes in such reporting system as INBio may reasonably request to ensure the accurate tracking of all materials.

6. INBio may have access to relevant laboratory notes relating to research activities involving INBio material.

7. The recipient shall submit periodical reports to INBio on materials, stage of the research, IPR, research results, etc.

8. The monitoring of uses is undertaken by staff of the Bioprospecting Unit. There is no Department or special personnel dedicated to the monitoring of contracts, this is done by the current scientific and technical personnel responsible for Bioprospecting tasks.

2.5.3.3 External transfers for biodiversity inventory

In general, all the types of samples located in INBio's inventory collection can be transferred to a third party, using a MTA and only for basic non-commercial research. This is mostly for taxonomic research which does not involve access to reproducible genetic resources. Transfers are made only to qualified collaborators. Each specimen has a bar code written in the sample form or MTA and monitoring is done through 1) reports from the recipient and 2) a requirement for the recipient to cite the barcode number of any specimens used in publications.

2.5.4 Costs of tracking resources through INBio

The database and barcode system effectively enable tracking, however the purpose of the system is not primarily for tracking, it is designed to associate information with the material to facilitate biodiversity research. Hence, the costs associated with tracking are difficult to separate from the wider research information management system.

Researchers at INBio do not routinely record publications citing INBio specimen numbers. No cost estimate is available for compiling or analysing reports from recipients on material used in taxonomic or bioprospecting research projects.

2.5.5 Conclusions: practical aspects of tracking microbial resources

INBio's practices for labelling biological material and tracking uses of the material within and outside Costa Rica show that it is feasible to label even individual insects *given sufficient resources*. INBio also maintains a database of agreements relating to collection and use of specimens including MTAs. The unique barcode number allocated to each specimen leaving Costa Rica could potentially be linked to a

certificate of origin number at minimal expense and with little technical modification to existing systems in INBio.

3. Comparative analysis

3.1 Types of genetic resources

Biological collections handle a diverse range of material, including either or both biological resources and genetic resources as defined in the CBD. Herbaria tend to hold plant and fungal material while museum collections may include animal, plant, paleontological, anthropological and microbial material. Microbial collections handle a diverse range of life forms and derivatives thereof with some definitions broadening to include even DNA sequences in electronic form In contrast to herbarium material and dead insects considered in other case studies, many microbial resources are living resources and instead of lending individual specimens, new specimens can be regenerated and passed on to subsequent users without return to the source. In this sense, microbial resources are comparable to live animals (zoos), plants (botanical gardens) or seeds (seed and gene banks).

One important issue, which is beyond the scope of the current study is the extent to which traditional knowledge, innovation and practices of indigenous and local communities may be considered to form part of biological and genetic resources. This issue is one requiring further analysis as the conditions for controlling access to and use of such knowledge, may require the extension of control over relevant biological and genetic resources.

3.2 Supply chain arrangements for genetic resources

An emerging response to the CBD has been for biodiversity collections to establish policies to implement the Convention's ABS provisions. Beyond institutional policies whole sectors are adopting codes of conduct or codes of practice. For example, a number of botanic gardens and herbaria have adopted a common code of conduct[25] and in the microbial sector, the MOSAICC initiative established a code of conduct for collections (BCCM 2001).

New material is typically collected under the framework of collaborative projects with partner institutions in the country of origin, which may have obligations on the distribution of the specimens. Collection activities thus often lead to material being dispersed amongst a number of different collections within a single institution (Figure 4) or in multiple institutions in difference countries. Even within institutions, different collections might get parts of a collection. Both Kew and the Smithsonian Institution, for example, house many separate collections apart from those described in the case studies presented here.

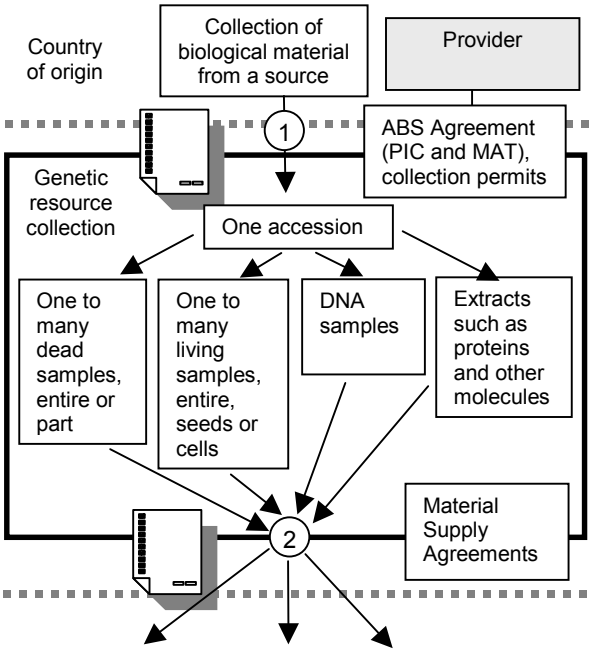

Figure 4. Generalised flow diagram for material entering and leaving biological resource centres.

[25] See for example: Principles on Access to Genetic Resources and Benefit Sharing: www.kew.org/conservation/principles.html. There is also the International Plant Exchange Network (IPEN) Code of Conduct – see www.biologie.uni-ulm.de/verband/cbd/index.html.

In many cases, accessions to collections are sourced from other collections rather from the field collection event itself. In this case a donation letter usually accompanies the material explaining the terms for its use, which historically had no conditions. These donations generally do not carry documentation of the PIC and MAT agreements under which they were collected, if indeed there are any. One microbial collection reported that no accessions for the last three years had been accompanied by PIC[26]

The greatest percentage of material collected by herbaria, museums and microbial collections is for non-commercial basic research on biodiversity. It is the potential impact of an increase in bureaucracy without any concomitant increase in benefits which a certificate system may have on this type of research, which most concerns research institutions such as Smithsonian and Kew.

Providers are most specifically concerned with regulating collection activities which may directly or indirectly lead to commercial use of resources. It is the frequently hazy line between commercial and pure scientific research which has proved most challenging for regulators to define in a manner which can protect the interests of providers while avoiding the establishment of overly restrictive access procedures. In an attempt to overcome potential ambiguities Kew, for example has established a clear definition of commercialisation in its MSA's. However, this line is not always black and white, and historically, material collected for non-commercial purposes has been used for commercial screening. It is important that all collections organizations understand the changes in the global and national rules and develop internal policies and procedures that provide safeguards to providers. Even when this is done, there is still the important question of when the "commercial trigger" is set. Is it at the beginning of research with commercial intent,? at the point of finding potential utility that could have potential commercial interest or at the point of developing patents? Each of these trigger points have been proposed and the practicalities of each needs further examination.

3.3 Documentation and mechanisms to track genetic resources

Biological research is based on information associated with biological material, such as locality, and season of collecting. Without this information the material is practically useless. Hence, long established systems are in place to label specimens and have associated information locatable. In botany for example, collectors assign their name and a number to each specimen submitted to a herbarium. The way in which collections store information varies from low technology systems such as paper index cards to high technology barcodes for each specimen with databases that may be internet-based allowing limited public access to certain information. Increasingly, this information is being put into database format to facilitate research. To date however, most of the historical collections and collecting information is still in non-electronic form.

The INBio case study shows that there are not major differences in how different biological materials with different end uses may be tracked and traced, even if they are labelled differently. INBio is using the same procedures for plants, fungi and insects and the same procedures for bioprospecting for fragrances and agricultural pesticides. The ABSA for a pharmaceutical or a seedbank deposit can be generated in the same software (e.g. MS Word) and stored in the same database (e.g. Oracle).The major differences are in labelling methods e.g. an adhesive label or pin won't stick to a liquid but it can be attached to a container holding the liquid. However, it should be noted that biodiversity collections use a wide variety of software and hardware, so in practice there may be limited possibilities for harmonizing documenting procedures among collections housed in different institutions. Making certain that use restrictions "travel" with the specimen is the data and programming challenge that many collections institutions are currently grappling with. INBio is not directly comparable to many collections because it was created recently (1990) and hence it has developed in the electronic age and the post-CBD environment.

[26] Statement during a session of the 10th International Culture Collections Congress, name withheld.

3.4 Costs of tracking genetic resources

Little information is available on the costs of labelling and tracking biological resources. The cost of accession of a microbial culture has been estimated at US$2,500 to 10,000 but these costs include quality control, validation, long-term preservation and global distribution and the proportion of these costs which are due to managing information associated with specimens has not been reported.

For other collections, the costs range widely. While minimal data is needed simply for tracking purposes, most electronic systems (such as the Smithsonian's or Kew's) carry substantial research information within the data records. The Smithsonian did a project trying to assess what it would take to digitize the complete National Museum of Natural History collection, to "catalogue standards" or enhanced with as complete scientific information as possible. Their analysis showed that it will cost between US$3 to US$6 per specimen to get minimal data catalogued. This does not include the costs of the system itself (Oracle or like systems are not inexpensive), internet connectivity, the management costs, or the curation costs of the specimens. While the cost per specimen may seem low, the Smithsonian has about 85 million uncatalogued specimens or lots and may do about 500,000 transactions per year - hence the overall costs could be enormous.

At Kew it was estimated that databasing all of its 53,000 herbarium specimen transaction per year in association with a certificate of origin number and associated data would require a minimum of 9.5 additional full-time staff plus significant staff costs and information storage and retrieval overheads. At the Millennium Seed Bank, additional costs of associating transactions with a certificate of origin number would be significantly less because all material is already databased.

At INBio, most material is databased in a way that allows for tracking of incoming and outgoing specimens. However, the database was designed for information management for research purposes generally and the proportion of costs that can be attributed to tracking is difficult to calculate.

Many collections around the world have developed databases in recent years. Many have been collaborating in the Global Biodiversity Information Facility (GBIF) to create standards and procedures for sharing information and making their databases interoperable. This system, including internet access and data interoperability infrastructure could be the basis of the user or intermediary side of a certificate of origin system as described in Figure 6. Working with national authorities to link to issuance of a Certificate would be a necessary part of any successful system. Estimates of the additional costs would greatly inform the discussion of the practicality, feasibility and benefit to cost ratio of adopting a paperless certificate of origin system.

Estimates of institutional costs would inform discussion of the impact of a certificate of origin system on institutions that handle genetic resources. Since cost structures vary between countries, a range of estimates beyond the three institutional case studies presented here would be useful. Furthermore, consideration needs to be given to the alternative uses of the resources which may be consumed by the establishment of a complex system of certification, including the costs of foregone scientific study, capacity building, and benefit sharing.

Further work is needed to evaluate the potential costs of increased documentation requirements. This may take the form of studies of current documenting costs of biodiversity collections. Alternatively pilot studies may be carried out to simulate how biological specimen data is recorded and handled and then infer what the impact would be on an actual biological collection. Alternatively, research could examine other sectors e.g. postal or courier material, and try to infer back to biological collections.

In developing any certificate system it may not be necessary to develop a one size fits all system for the internal management of data, but just to ensure that at entry and exit points the relevant data regarding any certificate is available and is recorded, to ensure that what goes out can be linked to what came in. One approach may be the establishment of some general minimum criteria for management of documentation internally while leaving the technological means for the relevant institution to decide upon.

This would reduce the possibilities of requiring retooling by institutions while allowing for a progressive harmonisation of data collection and management procedures.

The experience of INBio must be evaluated with due regard to the nature of that institution, the volume of resources it is managing and the objectives of its research and collection activities. This cannot be compared directly with the cases of Kew's Herbarium and the Smithsonian Institutions Museum of Natural History, both of which process many times more resources per annum from a wider variety of sources, subject to a multiplicity of differing legal obligations. INBio's focus on bioprospecting and commercialisation of resources creates a greater incentive for documentation of resources.

3.5 Practical aspects of tracking genetic resources

While costs of a certificate of origin system are difficult to estimate, it can be assumed that they would impact differently on different institutions. For collections that already have established databases and practices and resources for databasing all specimens, the incremental cost of a simple certificate number as described in Figure 6 would be minimal for new material. The case for pre-CBD collections is different and significant costs would involved in tracing permits PIC etc. For collectors and researchers a certificate of origin system could add additional costs to research projects. If acquisition of a certificate added much additional work to current PIC and MAT negotiations the additional cost could be prohibitive to basic biodiversity research.

Most biological collections are comprised mainly of material collected prior to the CBD. The vast number of specimens in this category makes it impractical to obtain PIC and MAT for every specimen which may be sent to other collections for research purposes. Much of the material has been collected over a period of hundreds of years and in for some cases, the country of origin may be unknown. For these types of specimens, a certificate of origin is likely to be unobtainable and a certificate of source may be the only option.

Introduction of a certificate of origin system would create an additional category of material for collections to handle. Handling pre-CBR, post-CBD but pre-certificate and post certificate material, each with different sets of legal restrictions, could add to administrative burden of institutions. A preliminary list of the information that may perhaps be included in a certificate of origin, has been proposed by Barber *et al*. (2003), these include:

- Particulars of the provider and user;
- Particulars of the indigenous or local communities parties to the agreement;
- Details of genetic resources or traditional knowledge;
- Details of the approved use which may be made of the resources;
- Details of any restrictions on use;
- Period of the agreement;
- Conditions relating to transfer of rights to third parties; and
- Details of the issuing authority.

The three institutions case studies reveal that in almost all post-CBD collections, all of this information is available in some form although rarely in one place and often at least some is restricted. However, for material received from other institutions, much of the information is not made available and the receiving institution has to rely on a document stating that the material was acquired legally (e.g. at Kew). Even where all the information is available to an institution most of it cannot be transferred to labels on specimens due to space limitations and hence it may not passed on to third parties. As the Kew and the Smithsonian case studies point out, many collections are for long-term, multi-generational use. They caution strongly against having use restrictions that are based on current practice and technology. Use restrictions that cover the needs for protecting genetic resource rights can be developed sensitively without creating problems for future basic science use of the collections.

Consideration of the benefit of developing a global system for documenting transfers of genetic resources should examine the potential of:

- Using existing tracking procedures where possible
- Minimising the creation of new levels of bureaucracy
- Promoting automatic issuing of relevant certificate upon compliance with specific criteria, such as completion of MTA or ABS agreement,
- Promoting consolidation of existing permitting requirements with any new certification system
- Promoting paperless systems
- Establishing minimum standards for the recording of collections, to ensure a link between incoming and outgoing resources, without requiring harmonization of internal recording procedures.
- Providing economic support to developing countries to develop online systems to support an international documentation system.

For non-commercial conservation uses, such as basic biodiversity research, there are many more international transfers of specimens compared to commercial users because no single country has the taxonomic expertise to identify the majority of organisms. In this sector, there are no monetary benefits to support an expensive tracking system and one option that has been proposed is to exempt these uses by creating a special category of uses exempt from certification. Care would need to be taken to ensure that any block exemptions did not create a loophole in the legal system or leakage in the system that allowed genetic resources to flow to commercial uses via the exempt sector without renegotiation of an ABS agreement. An alternative to creating exemptions for classes of uses of resources would be to place trigger points where certificates must be provided at stages in research and product development when it becomes clear that the use is no longer for basic research.

To some extent, technologies developed in other industry sectors may be applicable for achieving traceability of genetic resources. For example, systems for monitoring the IPRs over electronics, computer software and even music are well developed although instances of illegal use still occur. For some biological products like agricultural commodities there are quality assurance systems capable of tracking food from the farm to the supermarket. There already exist a range of international standards for biological products such as sanitary and phytosanitary (SPS) standards, food safety and labelling laws. For some other biological resources that are or have been traded, there is a certification system, the Convention on International Trade in Endangered Species (CITES). This is limited to border crossings of a selection of species when transferred among the 164 countries which are members of CITES and cases of illegal trade outside the system continue.

For biological specimens, the vast majority moved between countries are used for non-commercial research, not using the embedded genetic resources, or if they do, are using known genetic sequences for identification purposes. For new bioproducts discovery and creation, however, the supply chain arrangements are different, the value of the genetic resources component of the new product is poorly defined hence it can be difficult to demonstrate the benefit of an expensive tracking system, the timeframe from acquiring a resource to deriving any benefits may extend for decades or longer and in many cases it is more difficult to detect unauthorised uses of a genetic resource. Such considerations need to be incorporated into any cost-benefit analysis of a new system.

PART II – Developing a certificate of origin system

4. Framework for a system of certificates of origin

In determining the potential framework for a certificate of origin system a number of key issues need to be addressed, these include:

- The purpose of certification
- Nature of a certificate, i.e. would it be mandatory or voluntary
- Subject matter covered by the certificate
- What it is certifying – origin, source, and/or legal provenance
- When would it be required?
- What format would a certificate take – physical hard copy, barcode or virtual online certificate?
- What terms and conditions would apply to material provided under a certificate?
- What verification (trigger points) and compliance mechanisms would be needed to support such a system?

These matters can be addressed only briefly here, and focus will primarily be given to addressing the issues of the subject matter to be certified, the purpose of certification and a potential model for a certification scheme. A proposal is also made for utilizing certificates as a tool for promoting a more flexible access and benefit sharing procedure which incorporates elements of both liability and property regimes.[27]

4.1 Objectives

The nature, content and utility of any certificate scheme will depend upon the intended purpose of certification. A number of possible objectives for establishing such a system may be identified, including:

- Identifying the source of resources and/or traditional knowledge
- Establishing a standardized international system for traceability of genetic resources, to be used by herbaria, museums and microbial collections etc including commercial collections,
- Consolidating national permitting procedures, and reducing bureaucratic delay regarding exploration, collection, movement and exportation of genetic resources
- Tracking flow of resources and/or traditional knowledge
- Providing evidence of legal provenance
- Providing evidence of prior informed consent
- Assisting customs control of transboundary movement of genetic resources and/or traditional knowledge
- Providing legal certainty of rights to use resources
- Serving as a form of market tool to control market use.

Any certificate scheme should be designed to facilitate the realization of the CBD's ABS objectives. Certificates may be viewed either as a control mechanism to restrict unapproved use or as a tool for facilitating more efficient implementation of ABS regulations. Under the former view certificates are seen as a requirement to be imposed upon scientific and commercial users to prevent biopiracy, under the latter they may be viewed as a mechanism to reduce the complexities associated with access to and use of resources, providing legal certainty and reducing transaction costs. In the event that an international

[27] For discussion of the issue of property and liability regimes as they apply to ABS see Ruth Okediji, paper presented at the International Expert Workshop on ABS, Cuernavaca, Mexico, 24-27 October 2004.

certification scheme is to be adopted it should b designed to serve both ends helping to reduce unapproved use while simplifying compliance with ABS regulatory measures and thereby facilitating access to resources.

Access to genetic resources is important for food security and to create commercial opportunities from which benefits may flow. Any certificate of origin scheme would need to protect the interests of resource providers without being so restrictive as to prevent desired flows of genetic resources for scientific purposes linked to the conservation and sustainable use objectives of the CBD. Furthermore any system must not be so bureaucratic or costly that the transaction costs effectively consume potential benefits. There is already evidence that pharmaceutical companies are withdrawing from natural products research because of uncertainty of access (Dalton 2004). The number of new accessions to international agricultural genebanks has declined sharply since the CBD was ratified (Falcon and Fowler 2002) raising concerns for food security. A key question to be addressed therefore is whether a certificate of origin scheme would serve to facilitate or further impede access and benefit sharing.

For both conservation and commercial use, the benefits of any certificate of origin system would have to outweigh the costs. The main benefit for commercial users would be certainty of title to a genetic resource. This is critical to ensure that large R&D investments can be recouped. For non-commercial conservation uses, such as basic biodiversity research, there are many more international transfers of specimens compared to commercial users because no single country has the taxonomic expertise to identify the majority of organisms. In this sector, there are no monetary benefits to support an expensive tracking system and one option that has been proposed is to exempt these uses by creating a special category. Care would need to be taken with this approach to ensure that any exemptions did not create a loophole in the legal system that allowed genetic resources to flow to commercial uses via the exempt sector without renegotiation of an ABS agreement

The manner in which certificates are applied to trade and to science will need to be guided therefore by clear objectives which create the environment within which a technological and systematic solution to the issue may be sought.

4.2 Subject matter of a certificate

Certificates could be granted for the access contract itself and all material collected under it, for a specific collection activity in a defined area for a defined period, for all samples of a specific species or genus, or for an individual collection or sample. At another level a certificate might attach to a particular isolated compound, given an individual barcode, as for example is the case with samples provided by INBio. What will be necessary will be to identify the most practical level for the granting of a certificate and development of a system which enables collectors and or users to code the products of research and development in an identifiable manner which links back to the original certificate.

As the focus of any system will be to trace the flow of genetic resources it would seem at first sight that genetic resources themselves should be certified. The issue of definition of genetic resources is therefore of course important because there are a multiplicity of possible collections which would fit the CBD definition of genetic resources, including isolated compounds, soil samples, insect collections and animal and plant specimens. Where resources are readily identifiable and are the subject of specific agreements, in particular those relating to commercial use it may be appropriate that a certificate be linked to that specific resource. The issue is more complicated where collection activity focuses on wide-scale collection, in particular random collections and collection of resources which are as yet unknown to science. In such cases certification of specific resources is not only impractical it is virtually impossible either due to the lack of taxonomic information, the nature of the collection, for instance soil samples, or the random nature of the collection.

One alternative would be for certification of specific bioprospecting activities. Under such a system a certificate would be issued to cover all resources collected in accordance with a relevant access contract itself or, for a specific collection activity in a defined area for a defined period.

4.3 Nature of Certificate scheme

In considering the potential role of a certification scheme it is necessary to review a number of potential options, which are not necessarily mutually exclusive but may in fact be complementary elements of an overall certification system. These include harmonizing procedures for collating collections of genetic resources, tracking transboundary movement of resources and harnessing market tools for controlling the commercial use of genetic resources.

4.3.1 Documentation of resource collections

If certificates are intended primarily as a means for promoting harmonization in the procedures for documenting collections they would amount to no more than a codification system, and would be designed according to the needs of biodiversity collections. The benefit of greater harmonization in the procedures for collating collections to enhance data management and facilitate inter-institutional transfers is obvious.[28] If certificates are limited to this purpose they could be designed through a process which would seek harmonization of existing practices for documenting resources. It is worth noting that a process is currently under way under the auspices of the MOSAICS project to review existing practices for documenting resource flows in microbial collections in Europe.[29] The costs associated with developing and implementing a harmonized system, which required biodiversity collections to adopt the same internal systems for recording information may not be the most cost effective way of using scarce resources. The value of requiring uniform documentation procedures for the maintenance of collections for the purposes of benefit-sharing is also questionable; however, the case for minimum standards to ensure enhanced transparency and compliance with ABS obligations is clearer. Clear cost-benefit analyses are needed to see if the proposed solutions are viable.

While research has shown that the majority of institutions housing collections of biological and genetic resources maintain internal systems for identifying the source and or origin of resources, these systems show a high level of variance, even within collections within specific institutions. Variations between the use of paper and paperless systems, registering of individual specimens, batches, etc. make any question of the imposition of any harmonised system for codifying collections an issue of much concern and may be beyond the capacity and/or legal provenance of many national governments. Questions arise as to the necessity and benefits of imposing harmonised documentation requirements for the maintenance of collections. One of the greatest concerns is the cost implications of harmonisation. On the other hand it is clear that all collections need to identify ingoing and outgoing material, as a requirement for complying with obligations under the CBD, internal auditing and for ensuring that provision to third parties complies with the conditions under which resources were obtained. For this reason it is proposed that research should focus on the potential for developing harmonised requirements for the transfer of resources, and define minimum criteria for maintaining internal records of resources held in collections. Such a system would therefore regulate incoming and outgoing transfers while allowing flexibility as to the means adopted by individual institutions in maintaining internal records. Such a system may go a long way towards responding to the concerns of institutions such as Kew and the Smithsonian, while at the same time creating a system which will create incentives for progressive harmonisation of record keeping

[28] There are already initiatives, e.g. GBIF, under way to increase access to collections (by digitising specimens and making the images available for research via the www), without requiring institutions to use same systems.
[29] See: http://www.belspo.be/bccm/news/15-04/bccm02.htm; and Desmeth (2004) [paper presented at ICCC-10, Tsukuba, Japan.]

Developing a system of certificates of origin which links use of resources to standard terms and conditions of contract or otherwise identifies relevant terms and conditions for use of resources could help relieve scientific institutions of the burden of passing on to third parties all details relating to samples, some of which may be confidential. The institution would only be obliged to pass on the certificate number to enable traceability for the provider and access to limited information for prospective users. Concerns have been expressed regarding any system which would allow for the transfer of resources without requiring prior notification to the provider, and where appropriate their consent to any transfer.[30]

For collections such as Kew's herbarium where the entire collection, with rare exceptions, is made available to third parties under the same terms and conditions prohibiting commercialisation, a certificate of origin system will not be likely to vary the nature of transfers substantially, provided it does not require Kew to vary its policy of providing resources under its standard terms and conditions. However, it may lead to the development of more direct legal relations between providers and third party users. On the other hand, for some collections, like many in the microbial sector, there is a need to differentiate material which can be used for different purposes. A certificate of origin system would externalize some of the cost of this and add value to such a collection. Providers could track material past the first institution, third parties such as other collections could verify that material was obtained legally and potential users could identify who to approach for negotiation of PIC and MAT.

It is probable that in order to conform to any certificate of origin scheme institutions such as Kew may have to review their standard terms and conditions to ensure that they associate the use of resources with compliance with the terms and conditions attached to certified resources. The potential implications of such a procedure can at best be conjectured at present and further analysis of options for a certification scheme is merited.

4.3.2 Tracking transboundary movement of genetic resources

If certificates are to serve a role in the monitoring of transboundary movement of genetic resources and potentially traditional knowledge, there will be a need for development of formal procedures for the issuing of certificates, and for their recognition by customs authorities. Establishing harmonized documentation procedures at the global level will undoubtedly help the work of customs authorities, and serve to reduce the complexities associated with the importation and exportation of genetic resources and/or traditional knowledge. In such a case certificates would serve as a form of import, export and re-export permits, similar to CITES permits. A proposal for a permitting system for genetic resources similar to that under CITES was presented in the first months following the entry into force of the CBD (Downes 1993). A CITES type permit would require providers and users of genetic resources to comply with certain conditions for the access to and use of resources and for their transfer to third parties. CITES permits demonstrate legal acquisition of trade restricted products derived from endangered species, a valid permit is required for import and export as well as re-export.

The CITES system is open to abuse including corruption, forgeries, altered permits, misuse of documents and smuggling.[31] Cost recovery associated with the administration of CITES permitting procedures is also important. CITES is examining the possibilities offered by moving towards a paperless, computerized scheme. [32]

Access to and collection of genetic resources is currently regulated in most parts of the world through a series of exploration, collection and export permit procedures, most of which have been developed prior

[30] Intervention of Professor Gurdial Nijar Singh at the International Expert Workshop on ABS, Cuernavaca, Mexico, 24-27 October 2004.
[31] Marciel Yeater, intervention at the 2nd Paris Roundtable on ABS Governance: Certificates of Origin, Paris 9-10 November 2004.
[32] Ibid.

to the entry into force of the CBD. In many cases numerous permits must be obtained from a variety of national authorities in different Ministries to cover such issues for instance as research, collection in protected areas, and exportation. This multiplicity of permitting procedures greatly increases the costs of collections and efforts towards the consolidation of national collection permitting procedures are a key element of facilitating access as envisaged by the CBD. In examining the potential value of a harmonized international certification scheme it will be necessary to consider whether development and implementation of such a scheme might serve to help rationalize national permitting procedures and whether this is politically viable in source countries.

Documenting genetic resource flows for the purposes of controlling transboundary movements is already a requirement in many countries. Where those requirements could be met by provision of a valid certificate such a system should be designed to facilitate transfers, especially to third parties, reducing rather than increasing bureaucratic burdens reducing the need to provide supplementary documentation regarding access and export/import permits, other than those required for sanitary and phytosanitary purposes, etc. A certificate of origin scheme may go further than merely regulating cross border transfers and may be used for establishing a chain of custody trail which would follow the flows of resources not only across borders but between and amongst users, such as is the case with CITES permits..

Certification should not be considered as a system in itself but rather as an element or tool of a global ABS regime.[33] Therefore, any certificate system would be complementary to ABS regulatory mechanisms, including access laws and user measures. The requirement for obtaining and presenting certificates could be set either by national law or by international law.

4.3.3 Certification as a market tool

An alternative to requiring all genetic resource flows to be accompanied by a certificate of some sort, would be merely to require the disclosure of the use of genetic resources and traditional knowledge for various product approval and IP grant procedures, as well as disclosure of the origin and legal provenance of the resources. In this system the user may adopt various different means for demonstrating compliance, including provision of copies of any ABS agreement, copies of collection, and export permits, or evidence that resources had been legally obtained from an ex-situ collection.

Using a certificate scheme to control commercial use of resources may be likened to using a market tool to control market use.[34] Using certificates as a market tool implies creating an economic incentive for users to seek resources covered by a valid certificate. In this case certificates would serve to demonstrate not only the origin of resources but also the right to use them for specific purposes. Creating a market incentive for users to seek certificates would also create an incentive for providers to develop and adopt the measures necessary for the issuing of certificates. Use of resources may be linked to requirements to provide certificates to demonstrate the right to use resources under various regulatory and non-regulatory product approval processes, as well as in intellectual property grant procedures.[35]

Under a pure market based system the discretion as to when to obtain a certificate would be left to the user, who would make a decision to seek the relevant certificate based upon commercial issues such as the potential future cost of not having one. Such a system would in effect allow the user to determine when to seek prior informed consent and would not seek to control all transfers of genetic resources but would rather seek to create incentives for users to seek PIC in order to be enabled to commercially exploit products developed using genetic resources. However, the conditions for a pure market system to work are not currently in place. Considering the lack of confidence prevalent in the existing genetic resource

[33] Intervention by Tomme Young, at 2nd Paris Roundtable on ABS Governance: Certificates of Origin, 9-10 November 2004.
[34] Tobin 1997, Ruth Okedji, intervention International Experts workshop on ABS, Cuernavaca, Mexico, 24-27 2004.
[35] Ibid

market it is unlikely that developing countries in particular will favour a voluntary regime. However, establishment of mandatory requirements for the provision of certificates of origin as a condition for obtaining product approval or for the processing of an IP application will have economic and other implications for providers of genetic resources, and they will need to assess the economic benefits of increased control as against the costs of administration.

Requirements to show the source and legal provenance of resources could be adopted to apply not only to CBD material but also to resources collected prior to entry into force of the CBD within national legal systems.

Proposal for utilisation of certificates of origin as a market tool is based upon five fundamental premises:

- National jurisdictional boundaries limit the power of countries of origin to control the use of genetic material and of associated knowledge outside of their jurisdictions;
- Scientific, commercial and industrial users will not invest large sums of money in the research, development and marketing of any product unless they can secure IPR protection for their investment;
- IPR regimes may require a sworn declaration as to inventorship, and a detailed description of how the product was made. At this stage, the use of genetic resources and associated knowledge should come to light but due to less than adequate specification procedures this will be unlikely to occur in many instances[36];
- Policing IPR regimes in order to monitor the use of genetic resources and associated knowledge is beyond the capacity of all but the richest of companies and nations; and
- Existing IPR regimes are inadequate for the recognition and protection of indigenous people's traditional resource rights[37].

4.4 Certificates of Origin and Trade

Questions arise regarding the imposition of mandatory requirements and the compatibility with International trade law under the WTO. One recent study of the relationship between certificates of origin and the WTO has suggested that in order to ensure consistency with WTO rules any certification system should:

- Be designed on a product basis, not on a country or firm basis, with certification travelling with the resources along their useful life
- Be mandatory for the sale, use, export, import, and/or patenting of a product
- Ensure that where certificates attest not only the source of resources, but also compliance with benefit sharing standards, those standards should be established by providing countries.
- International coordination of a certification scheme would improve its effectiveness and reduce the risk of a WTO challenge.[38]

Potential conflicts with WTO are only relevant if a system of certificates is mandatory. Mechanisms for controlling access to and use of genetic resources in both provider and user countries will create regulatory controls over resource exchanges and flows. A certificate system which merely serves to demonstrate compliance with the requirements of the laws of the providing country, legal title to use

[36] Gadgil and Devasia, draft paper, 1995 (Reference to be provided).
[37] Mooney, 1994; Posey, 1994; and Brush, 1994, p. 137. For further discussion of the problems with existing IPR regimes and of possible alternative mechanisms for protection of indigenous rights see Greaves 1994, Mooney 1994, Nijar, 1994, Shiva and Holla-Bahl, 1993; Lesser, 1994; Tobin, 1993 and Tobin, 1994 (References to be provided)
[38] Louafi, Selim and Jean-Frederic Morin: Certificates of Origin for Genetic Resources and International Trade, paper distributed at the 2nd Paris Roundtable on ABS Governance: Certificates of Origin, 9-10 November 2004.

resources and identify the rights and limitations attached to any access and use, would not in itself appear to run counter to WTO rules. This is particularly so where the certificate itself was not a condition for the transfer of resources, but merely served as one of a number of potential mechanisms for demonstrating compliance with legal obligations regarding access to and use for genetic resources. Terms and conditions governing the use of resources will normally be set out in an agreement for access, national ABS law and user measures, and under any international regime. Acceptance of resources which are linked to a certificate may however be taken to amount to acceptance of the terms and conditions for use associated with the relevant contract, or national terms and conditions under which the rights of access were originally certified. If there is national legislation in the provider country then requiring compliance with such legislation in the user country will probably be sufficient. In the absence of national legislation in provider countries there is a need for an international system.

The issues which will need to be considered in the context of potential impacts on trade, include whether certificates will apply to transboundary movement of genetic resources or of products including genetic resources. If obligations extend to products including genetic resources the question arises as where to draw the line with regard to the need to show certificates. Another important issue relates to where compliance is being required, i.e. in the provider or recipient/user country. If it is in the user country it is more complicated and may run foul of WTO rules, however, there is need for care not to artificially construct a link to WTO.[39]

Building international support for the implementation of a certificate system will be important and multilateral regime is the most appropriate to overcome potential concerns with regard to WTO as well as to provide protection for countries which do not have relevant national ABS legislation.

The debate on certificates of origin has many parallels with the ongoing debate on MTA's under the International Treaty on PGRFA, and there is good reason for the SCBD to approach FAO to discuss the sharing of experiences in the investigation and development of these potentially inter-related systems. The SCBD might also consider inviting the WTO to provide input for consideration of the potential trade implications of an international certificate of origin system.

4.5 Model for a certificate scheme

During the negotiation of amendments to the Bonn Guidelines during COP VI in The Hague, the term certificate of legal provenance was first mooted as an alternative to the term certificate of origin. The term found favour with those concerned that identification of the origin of resources might prove problematic in many cases and there was a need to develop a system which could recognize that many resources were now legally held in collections outside their country of origin. Mexico and Costa Rica in particular promoted the idea of certificates of legal provenance. Two recent papers on the role of certificates of legal provenance have described them as being complementary to a certificate of origin. The latter would provide evidence of the source/origin of the resources, and could perhaps be provided by the actual provider of resources while the former would provide evidence of the legal right to use resources, and could be issued by a relevant national authority.

Another proposal has suggested a further level of certification to demonstrate compliance with international obligations.[40] Establishing multiple layers of certificates is likely to increase concerns of potential users regarding the costs and bureaucracy associated with its implementation.

Proposals have also been made for certification of source rather than of origin on the basis that origin may be impossible to identify. A certificate of source would track the genetic resource only as far as the place

[39] Communication with Heike Baumuller, Paris Roundtable on the Feasibility, Practicality, and cost of Certificates of Origin, 10 November 2004.
[40] Louafi and Morin (2004) (Reference to be provided).

where the user obtained it, which may be a collection or depository and not necessarily the country of origin. A certificate of legal provenance would document evidence that the resources had been obtained from a legally entitled provider. In the face of continuing uncertainties regarding legal rights over resources and absent a binding international regime on ABS which clarifies the legal status of all pre-CBD collections and of those collected post CBD but without PIC, legal provenance would fall to be decided by the laws of the country where the resources were sourced. This situation could potentially provide an opportunity for circumvention of the rights of countries of origin. The following discussion considers the potential role of certificates of source, legal provenance and origin and suggests they may each have a role in a comprehensive certification scheme.

4.5.1 Comprehensive certification scheme

Attempting to secure international accord on whether a certificate of source, legal provenance or origin is to be preferred would not appear and easy challenge to overcome, nor is it necessary a valuable one to pursue. In fact, a system which employs a variety of certificates including both certificates of origin, and legal provenance, as well as, potentially, certificates of source may be the most effective way to expedite the establishment of a functional international system.

A number of fundamental questions which need to be addressed by any certification system are: first, the scope of any regime, whether it will apply to batches or specimens, and commercial and/or scientific research, secondly, how to demonstrate clean title to resources and support the sovereign rights of countries of origin; thirdly, how to deal with resources covered by the CBD and pre-CBD collections; and, finally how to bring into the remit of any system private collection of individual scientists and research institutions. A question of much importance which is beyond the scope of the present study, but will be addressed in future research by UNU-IAS, is how any system should deal with traditional knowledge related aspects of biological and genetic resources.

One of the great tensions in the present debate on ABS is between industry and countries of origin. A certificate system may serve to create a greater synergy between the interests of both, with regards to access to resources, research and development and benefit sharing. One of the main beneficiaries of a standardized system for demonstrating the origin of biological and genetic resources and of rights to use them would be the private sector. A certificate of origin system which provides evidence of a clean title for use of resources would enhance the value of resources and create greater private sector interest in the natural products market. At the same time, a system of certification would provide increased transparency, facilitate monitoring of use of resources and of compliance with ABS agreements, responding to the interests of provider countries.

Any system which does not apply to all transfers of biological and genetic resources will create loopholes which may undermine realisation of the CBD's ABS objectives. Failure to cover resources collected prior to the entry into force of the CBD will create uncertainty over rights to use resources, reduce the value of legally held collections, lead to continuing controversy over biopiracy, and impede the development of the market in genetic and biological resources. Creating a system to help demonstrate legal rights to use resources will impede illegal uses, create incentives for investment in legal bioprospecting and provide legal certainty for commercial users. Creating a system which applies to all biological and genetic resources will require that collections review the status of material obtained prior to the CBD, to determine the legal rights and limitations relating to its use, in particular where it is utilized or provided for use for commercial purposes. For instance material provided for scientific research purposes without any explicit right for commercial use, may need to be made subject to greater restrictions if transferred to third parties than is the case for material which was provided with complete freedom for use. It will be particularly important to identify resources which may be the subject of rights associated to traditional knowledge to which customary laws and practices of indigenous peoples may apply, creating special conditions regarding resource use.

A further area of concern relates to the large amounts of genetic resources held in private collections, in universities and other research centres as well as by individual scientists. The origin of some of this material, especially where collected prior to the entry into force of the CBD, may be unknown and there may be little if any documentation to demonstrate the rights to utilise such resources. Where no clear legal title can be demonstrated a question arises as to whether possession is to be considered nine tenths of the law or whether the obligation to demonstrate a legal right to use these resources for future research and development activity lies with those claiming such a right. Any system should seek to develop mechanism which will facilitate the scientific sector to progressively bring their collections into the framework of a certification system without paralyzing ongoing research. This is particularly important in regards of basic research efforts where high costs associated with identifying the origin and rights over resources may effectively lead to a suspension of research activities.

In order to respond to these three challenges, i.e. to establish clean title for resources obtained under the CBD, enable the continuing transfer and use of resources collected pre-CBD for which there is a clear legal title, and to progressively incorporate private collections utilised for non-commercial purposes while enabling such research to continue unimpeded, a comprehensive certification scheme is proposed. This scheme involves the use of three types of certificates. These are certificates of origin, certificates of legal provenance and certificates of source.

A Certificate of Origin would be granted by a national authority in the country of origin of biological and or genetic resources and would demonstrate that access was the subject of a valid ABS agreement.

A certificate of legal provenance would demonstrate that the resources subject of the certificate were legally held and were provided for use in accordance with the terms and conditions under which they were obtained.

A certificate of source would be provided to accompany any transfer of resources for basic non-commercial research.

A certificate of origin or a certificate of legal provenance or other valid evidence of the legal right to access and use resources could be required for scientific and or commercial research and development purposes. A certificate of source would only entitle basic non-commercial research. To the greatest extent possible a system of certificates should act as an incentive based mechanism to promote research activity. To this end check points for the presentation of certificates and the control of research should be reduced to a minimum. A system of certificates which operated as a form of shrink-wrap licensing to facilitate research activities, subject to the compliance with a standard set of terms and conditions including benefit sharing obligations could help to reactivate the natural products research industry, and generate greater benefit sharing opportunities.

A certificate of origin would most likely be granted by a national competent authority as evidence of the existence of a valid agreement for access to genetic and biological resources. The value of a certificate of origin would be to clearly establish clean title to resources and establish a fresh chain of custody for genetic resources obtained in accordance with the CBD's provisions on ABS; add value to resources by ensuring legal certainty for users; and to distinguish material for tracking and for marketing purposes. It is conceivable that resources which are covered by a certificate of origin may in time become more valuable as users seek to ensure the legitimacy of the source and to avoid any potential claims of biopiracy.

A certificate of legal provenance might be issued by a provider of the relevant genetic resources such as a genebank, herbarium etc. Their right to grant such a certificate could be established by a national approvals procedure. Holders of genetic resources which meet certain specified standards for the maintenance of their collections could under such a system be entitled to grant certificates of legal provenance, for resources within their collection that meet clearly defined criteria. This could include material collected prior to entry into force of the CBD, material collected in accordance with international agreements, or material obtained in accordance with national law in countries not requiring PIC and MAT

for access, and for which it can be shown that resources were obtained in full compliance with national law and policy of the country of origin, or other provider with clear legal title to these resources. Certificates of legal provenance might also be granted by a national authority in a country other than the country of origin, for resources held by individuals or companies which are not registered, subject to provision of evidence of their legal acquisition of the relevant genetic resources. Certificates could define rights of use and should include reference to any obligations and restrictions on use which have been placed upon resources by the terms and conditions under which they were originally obtained.

One of the major concerns of the scientific sector is that the establishment of a certification system may bring to an abrupt halt all transfers between scientists for basic research. The challenge will be to progressively introduce more accountability to the scientific sector in how it transfers resources, while at the same time avoiding undesirable negative impacts on basic research. One option would be to utilise certificates of source to cover transfers of material presently held by scientists for non-commercial purposes. In these cases the certificate of source would indicate the manner in which the individual or organization wishing to transfer the relevant resources had obtained the resources and the conditions applying to these resources (specifically non-commercial use of the specimens). This would serve to provide a paper trail of resource transactions, which could be traced for the purposes of identifying whether the resources were legally held or not. This might for instance be utilized for exchanges between scientists for basic research. Certificates of source could be required for all exchanges of genetic resources for scientific research purposes not covered by certificates of origin or legal provenance, and would help to develop a more responsible management of resource flows amongst scientists. Such certificates could not be used as the basis for commercial use of resources and, in the event of serendipitous innovation, it would be necessary to seek a valid certificate of legal provenance or of origin prior to seeking a patent or product approval etc. A system of certificates of source is likely to find favour with biodiversity collections which provide access to resources for primarily scientific non-commercial research, however as many collections already develop a paper trail at the level of MSA's the question arises as to what incentives might exist for them to change to any new system.

Establishing a system of certification which provides for a variety of certificates which can respectively demonstrate the of source, legal provenance or origin may prove more feasible as a means for launching comprehensive system for tracking resource flows than trying to establish a single form of certification to fit all situations. Such a system may be implemented progressively or establish a requirement that from a specific date all future transfers of genetic resources for commercial and/or scientific purposes include the provision of clear data on the origin, source and or legal provenance of resources. Alternatively, requirements might be applied first to commercial uses and progressively introduced for the scientific sector.

These requirements should apply to all transfers but need not be required for transfers within a specific research institution provided that the obligations relating to the use of the relevant resources are complied with in full.

4.5.2 Disclosure of Origin

Proposals for establishment of disclosure of origin requirements in national and international intellectual property rights regimes have become part of the mainstream debate on implementation of ABS and TK regimes in many important forums including CBD, WIPO and the WTO. Mechanisms have been adopted requiring disclosure in numerous countries of the developing world including the Andean community, India, and Costa Rica as well as in a growing number of developed countries, most notably Denmark and Norway the latter requiring disclosure of both origin and of evidence of PIC. Proposals have been made by India and Brazil and a host of developing countries at WTO, for amendment of TRIPS to include a mandatory requirement on disclosure of origin, Meanwhile Switzerland has proposed an amendment to the Patent Cooperation Treaty for a voluntary regime.

The functioning of any disclosure regime will require patent officials to determine whether the origin of resources has been adequately disclosed, and where appropriate whether PIC for use of resources existed. It is not hard to see that patent officers will be uncomfortable about assuming responsibilities where they may lead to burdensome and time consuming evaluation of issues beyond their area of capacity.

A standardised international system of documentation to record the origin of resources and where appropriate of PIC for their use would make their task much easier as the document would serve as evidence of both origin and PIC. This would not mean that providers of resources would be bound to provide certificates of origin as a condition for granting access to resources, nor that applicants for patents would be bound to provide them as evidence of origin or PIC, which could be evidenced by other forms of documentation. However a streamlined process involving standard documentation is likely to be welcomed by patent officials.

Many products are not covered by patents however other regulatory processes such as drug, seed and other product approval systems, also lend themselves to controlling use of resources and may help promote compliance with ABS laws. Similarly if scientific journals were to require evidence of rights to work on relevant genetic resources or traditional knowledge, as a condition for acceptance of articles this would prove an important inducement for scientists to ensure they have obtained rights to use relevant resources. In all such cases a certificate of origin could serve to demonstrate the right to use resources.

The benefit of certificates for the private sector would most clearly be to provide legal certainty regarding the right to use resources. Such a system could also help provide greater security for providers when linked to a licensing regime such as has been described above. Development of any certificate system should be carried out with an eye towards promoting greater transparency, flexibility and mobility in the international flow of genetic resources.

By requiring the inclusion of evidence of PIC as a condition for processing an IPR application, the user it is argued will be induced to comply with national access laws and secure approval of communities for use of collective property.[41] This is particularly true if the failure to make a true declaration, or to use reasonable endeavours to identify and receive consent for access and use from a legitimate source, could lead to revocation of any IPR granted, or prevent the exploitation of the patent, for instance through the application of the Doctrine of unclean hands[42].

The application procedure, employed in many patent and PBR regimes, could be extended to include resources used and evidence of the legal right to use them. Such evidence could be made in the form of a certificate, issued by the competent authority of the country providing the resources. This certificate would include the names of the parties, the tangible and intangible resources being provided, and the rights and limitations placed upon the user. Although it will be difficult to prevent the falsification of certificates, the danger of losing IPR protection will induce most users to secure legitimate approval.

A certificate system common to all nations would help to harmonize procedures and prevent the need to interpret different contract provisions under differing legal regimes[43]. It would also protect commercial confidentiality of sensitive contract details not required by the patent authorities. A uniform and recognizable certificate would also help to prevent the necessity for verification of the nature of the consent given. These may be denominated as certificates of origin[44]. Requiring applicants for patents and

[41] Tobin (1999) (Reference to be provided).
[42] For discussion of the doctrine of unclean hands see Barber *et al.* (2002); Carvahlo (Reference to be provided).
[43] Reid, Barber and La Vina 1995, p. 10.
[44] The term certificate of origin was first adopted in reference to this proposal during the IUCN/SPDA project to prepare a technical report on elements for inclusion in a Decision on a Common Regime to Govern Access to Genetic Resources, for the Andean pact. Elements of the proposal have been included in the Andean Pact draft Decision on Access to Genetic Resources, and their idea has also been presented in many fora including the Symposium for Indigenous Peoples of Latin America "Indigenous Peoples, Biodiversity and Intellectual Property",

other IPRs to make a sworn declaration regarding the use of genetic resources and associated knowledge, and provide evidence of their legal right to use such resources for the production of the material for which IPR protection is sought, would in effect shift the burden for demonstrating the right to use resources from countries of origin of genetic resources and indigenous local communities to the user[45].

Similar requirements could also be included in product approval procedures. The Food and Drug Administration and the International Standards Organization, for example, could make evidence of PIC a precondition for receipt of applications. As many products not subject to patents are commercially exploited at an industrial scale, it is important that mechanisms be developed to control all major commercialization of genetic resources, collective property, and products developed with use of such resources.

Certificates of origin would provide clean title with regard to use of resources and the veracity of the certificate could be checked through an online system. A certificate of legal provenance could also serve as evidence of a right to use resources for a commercial purpose. In the case of the provision of certificate of legal provenance the patent authority could inform the authorities in the country of origin of the submission of the patent application and of the relevant certificate of legal provenance. This would provide an opportunity to challenge the certificate if desired. A certificate of source should not be considered adequate provision of information regarding the right to use a resource for commercial purposes, and supplementary evidence could be required to substantiate rights to use relevant resources.

4.6 How would a certification system operate?

One potential mechanism would be to grant a certificate for all samples collected under a particular agreement. The contract would be registered with the competent national authority and would be accessible for consultation with regard to the terms and conditions applying to samples covered by the particular certificate. All collections made under the relevant agreement would be coded with the certification number applying to the original contract, to which would be added a number to identify specific collections, samples etc. At subsequent stages in research and development additional codification could be added to identify specimens, isolated compounds, etc. As all extra codification procedures have implications for the costs of management of collections, efforts should be made to minimize the need for varying the use of original codification numbers associated with a certificate. It is conceivable that original collections, batches, individual specimens etc may be covered by the same certification number.

In such a case, the original certificate would accompany all subsequent transfers of relevant genetic resources. Transfers may be made conditional upon a commitment to notify the competent national authority in the providing country. In order to ensure that any regime facilitates basic scientific research while preventing unapproved commercial use, a multilateral agreement might seek to establish varying notification requirements depending upon the intended use of resources and the designated recipient. In some cases, a form of block exemption may be put in place allowing the free transfer of resources without a requirement for prior approval, while in other cases transfer may require prior informed consent of the country of origin.

Transfer of resources to third parties, where allowed under the original agreement, could be made subject to the terms and conditions of the original agreement, a set of standard terms and conditions established by the providing country's competent national authority, or minimum terms and conditions specified as a

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Santa Cruz, Bolivia, 28-30 September, 1994, where it was considered worthy of further consideration, see COICA, 1994. See also Environmental Resources Management Workshop, 1996.

[45] This may be likened to the reversal of the burden of proof regarding production of a product over which there exists a patented process, found in many jurisdictions and as included in the TRIPS agreement of GATT. See Espinosa, 1992.

condition for the original collection activity.. In this case a certificate of origin might be likened to a MTA and would serve to put the recipient on notice that use of the relevant resources is governed by these terms and conditions. In this sense the certificate of origin would serve as a form of shrink wrap licensing regime. The result could be to significantly free up the flow of genetic resources while ensuring legal certainty for users as to their rights to use resources and security for providers that their resources were covered by legal obligations.

It would of course be essential that "user measures" are in place to ensure compliance with licensing conditions. Failure to comply with the terms and conditions of the agreements associated with relevant genetic resources would amount to a clear case of biopiracy.

4.7 A passport-type physical certificate

One potential embodiment of a certificate of origin may be likened to a passport that accompanies genetic resources, either through their entire history from collection to use ('cradle to grave') or for certain transactions such as patent applications or product approval procedures. Possible check-points for a certificate could be at borders (Figure 1), patent offices or the registration points for other commercial applications not covered by intellectual property rights.

The actual format of a certificate could either be paper, bar-coded or perhaps more functionally for organizations carrying out high levels of transactions by way of virtual online certificates (Figure 6). Notification of transactions and transfers to the providing country by way of an online register of resources would potentially reduce the administrative burden of such a system while ensuring the maintenance of a clear trail of resource disbursements. It may be necessary to develop a system by which resources may be retired and any reporting obligations associated with the use of resources terminated with regard to certain resources, when they are no longer in use.

One application of a certificate of origin would be to verify that cross-border movements of genetic resources are incompliance with the laws of the exporting and importing countries. The way this might operate is illustrated in Figure 5. To trace the movement of resources a number of technologies may be applied. These range from simple paper documents through to electronic tags which are integrated with internet-based databases.

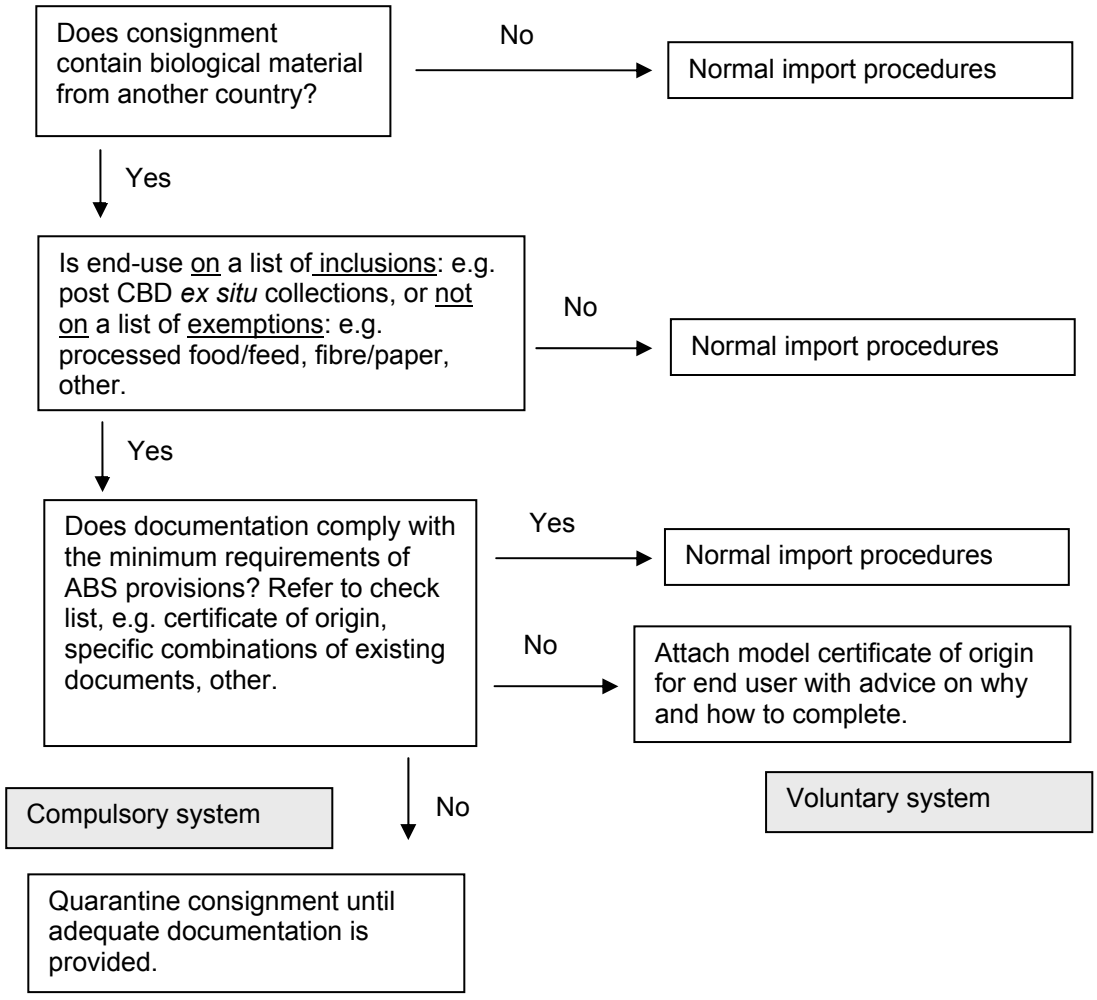

Figure 5. Hypothetical decision tree for processing cross-border movements of biological material under a potential certificate of origin system. (prepared by B. Cunningham)

The problem with this type of system for biodiversity collections is that samples are often partitioned which could necessitate the production of many copies of a certificate. Questions could be raised about the authenticity of copies and in any case the administrative burden and cost could be prohibitive for many collections.

4.8 An internet-based system of certificates

One way in which a traceability system for genetic material might work is through a standardised electronic document which need not physically accompany the material to or beyond the first user. The document would provide evidence that an agreement to use the material exists and users could confirm the conditions of use through a distributed database of certificates (Figure 6). A reference number to the original certificate would suffice to enable users or regulators to verify the terms of use via the internet. A method of physically labelling material would still be required to associate material with a certificate number.

In practice, any country could establish its own certificate of origin database, advantages could be obtained through standardising a minimum set of data fields but additional fields would likely be required

for most countries to handle differences in legislation and also differences between types of genetic resources.

The standardised data set would inevitable need to be revised to cope with future developments, this is normal practice for traceability systems such as vendor declarations that have new editions published from time to time.

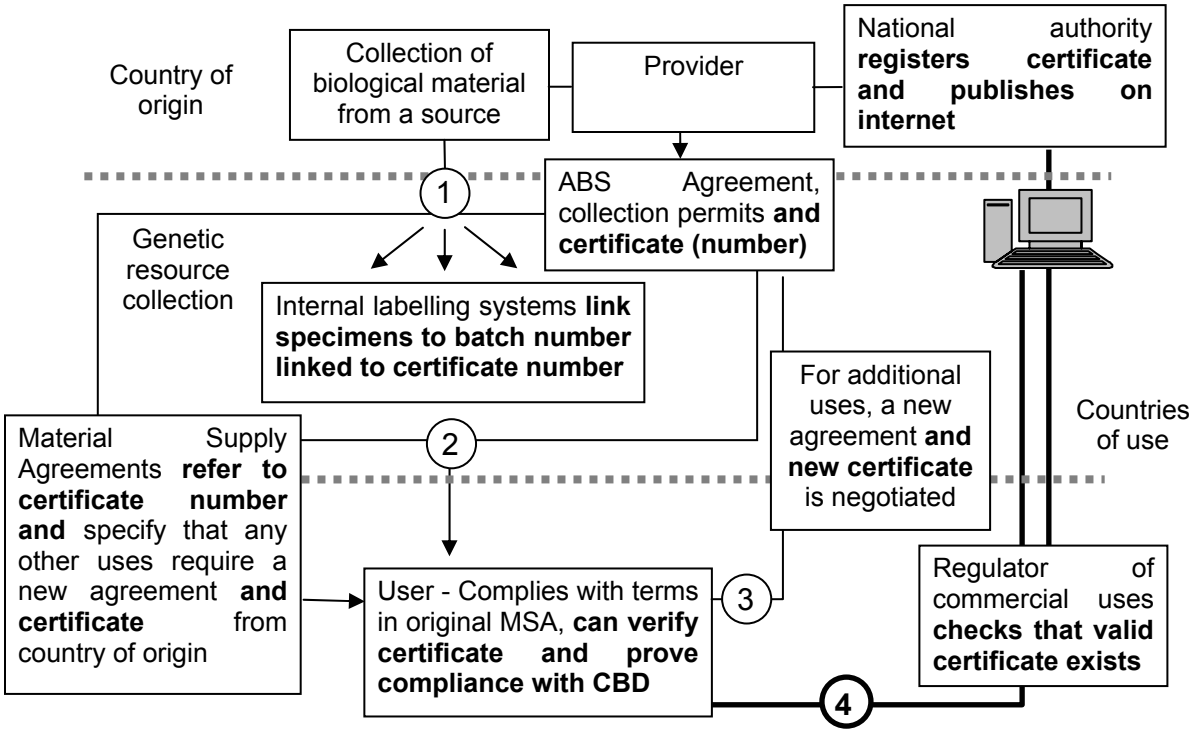

Figure 6. Hypothetical model of certificate of origin traceability system for genetic resources (new elements in bold font). (prepared by D. Cunningham)

5. Conclusions

Any certificate of origin scheme would need to protect the interests of resource providers without being so restrictive as to prevent desired flows of genetic resources for scientific purposes linked to the conservation objectives of the CBD. Access to genetic resources is also important for food security and to create commercial opportunities from which benefits may flow. Furthermore any system must not be so bureaucratic or costly that the transaction costs effectively consume potential benefits.

The collection, movement, storing and transfer of biological and genetic resources is subject to a wide array of permitting and approval procedures. These involve extensive bureaucracy and human and economic resources to maintain, and involve a range of mechanisms for the documentation, monitoring and control of exchanges and use of resources.

A significant majority of biological and genetic resource collection activities and transfers are for non-commercial purposes related to basic science. Permitting procedures are already in place in a majority of countries to regulate the activities associated with such collection activities and the export of samples these procedures often involve costly and time consuming procedures involving a number of differing government agencies.

Biological and genetic resource collections employ a wide variety of mechanisms to document the resources they hold. These range from paper to electronic records and from batch to individual specimen records. Collections would benefit from the rationalization of access, collection, export and other permitting procedures.

A standardized international system for documenting the origin, source and/or legal provenance of biological and genetic resources could help to facilitate access to genetic resources and transfers between and among collections. However, harmonisation of internal record keeping among collections globally would involve significant investment of technological human and economic resources, which may outweigh the benefits obtained for both providers and users. Any system of certificates of origin may therefore be designed to focus on establishing a harmonised system for documenting genetic resource flows up to the point of entry into individual collections and at the point of exit. Any requirements relating to internal record keeping associated with biological and genetic resources should be minimal and only such as is necessary to ensure that the maintenance, use and transfer of resources to third parties is made in accordance with the terms and conditions under which they were obtained. Internal and external transfers should ensure that the relevant resources are always linked to the original certificate of origin.

The objectives of certification may include the collation of collections, control of transboundary movements of resources, and establishment of market tools to control commercial use of resources. The existing level of knowledge of biological and genetic resources and the nature of collection activities makes the certification of individual resources at the point of collection impractical, costly and in many cases impossible due to a lack of taxonomic information. Certification of collection activities or of all resources collected under specific ABS agreements may be more practical with a single certificate applying to a myriad of resources, linked back to a set of standard terms and conditions. Specific certificates for endemic or other highly valuable resources may be provided together with customized contractual arrangements.

Three areas of particular concern in the design of any certificate scheme will be to find synergy between the interests of providers and users, cover both CBD and pre-CBD collections and progressively create a chain of custody for resources held by individual scientists and held in private collections. In order to respond to these three challenges, a comprehensive scheme involving use of certificates of origin, certificates of legal provenance and certificates of source is proposed.

To the greatest extent possible a system of certificates should act as an incentive based mechanism to promote research activity. To this end check points for the presentation of certificates and the control of research should be reduced to a minimum. A system of certificates which operated as a form of shrink-wrap licensing to facilitate research activities, subject to the compliance with a standard set of terms and conditions including benefit sharing obligations could help to reactivate the natural products research, and generate greater benefit sharing opportunities.

Disclosure of origin of genetic resources in patent applications is being adopted in an ever widening group of developing and developed countries. A certificate system could serve to support such disclosure of origin requirements, with both certificates of origin and legal provenance serving as evidence of a legal right to use resources.

Costs associated with maintaining a certificate of origin system should be recoverable for national authorities in provider countries. However, since the major users are also underfunded organizations, creative financing systems from the commercial interests may also need to be developed. Due to differing technical capacities and the status of many existing collections any system will need to employ a variety of mechanisms for documentation purposes, Experiences in CITES and the World Customs Union suggest any system should focus on a primarily paperless system.

The objectives of any system should be clearly worked out in advance of development of regulatory obligations for the use of any harmonised documentation procedures, the costs and benefits at all levels

and for all stakeholders needs to be carefully thought through. Due care should be taken not to establish a system which will impede developing countries from effectively participating in the market for biological and or genetic resources or which will cause disguised barriers to trade.

6. UNU-IAS future research

This analysis of how collections handle biological specimens suggests one or more potential models for an international certificate of origin system. Further research is required to investigate how these models could be implemented in practice. A detailed benefit-cost analysis of the implications of any certificate of origin system would help to identify the true potential of any model to help meet the objectives of the CBD on Abs, and support effective ABS governance. The best way to test a system will be through pilot studies. Case studies could be conducted with partners in a range of genetic resource provider countries to see how and if countries could implement a certificate system. The feasibility of implementing a certificate of origin system for traditional knowledge could also be investigated.

While traceability between institutions may be relatively simple, whole supply chains from geographic source to end use and marketing are more difficult to trace. Different industry sectors may have unique requirements of any certificate of origin scheme, e.g. biopharmaceuticals, cosmetics, timber and other fibres, horticulture, other agriculture and processed food. The feasibility of implementing a certificate of origin system by commercial users could be investigated through case studies of large companies, small companies and multinational companies that trade in, but do not use, genetic resources.

Key questions about certificates of origin include what event would trigger the issuing of a certificate, who could issue it, what could be certified, would it apply to individual samples or all samples covered by a particular contract or even individual genes, how could the information be stored and accessed, how far could a resource be traced in practice and what measures could be put in place for penalties, liability and redress. A fundamental question is what a certificate system is for, would it help users and regulators to facilitate the continuous flow of genetic resources while at the same time respond to demands for rights to resources and associated traditional knowledge under the CBD? If not, are there alternatives to achieve these outcomes?

Questions remain about what is the authority that can legitimately provide access and issue a certificate, what happens when a resource may be obtained from a range of countries and knowledge from a range of local communities in one or more countries, how far could a resource be traced in practice and what measures could be put in place for penalties, liability and redress and how traditional knowledge is certified.

All of these questions also apply to the related issue of traditional knowledge, innovations, and practices associated with biodiversity, which has not been addressed in this study.

Traditional knowledge can take both tangible and intangible format and transfer, storing and use of such knowledge poses more complex questions for monitoring purposes. Questions regarding who might issue any certificate of origin of traditional knowledge and to provide documentary evidence of the right to utilise such knowledge requires further research. Any work in this area should be carried out in close collaboration with indigenous peoples and local communities.

While research is necessary the need for implementation of a functional ABS regime at the global level requires action in the near future. Development of a certificate system to support the enhanced effectiveness of international ABS governance requires prompt attention, and could be adopted with a view to progressive implementation, regular review and modification as part of a process towards the consolidation of an international ABS regime.

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