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FRAMEWORK STUDY ON FOOD SECURITY AND ACCESS AND BENEFIT-SHARING FOR GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Submission by the Food and Agriculture Organization of the United Nations (FAO)

Note by the Executive Secretary

1. Further to the request of the Commission on Genetic Resources for Food and Agriculture, the Executive Secretary is pleased to circulate herewith, for the information of participants in the ninth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, a study entitled "The framework study on food security and access and benefit-sharing for genetic resources for food and agriculture" prepared at the request of the Secretariat of the Commission on Genetic Resources for Food and Agriculture and considered at its Twelfth Regular Session.

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

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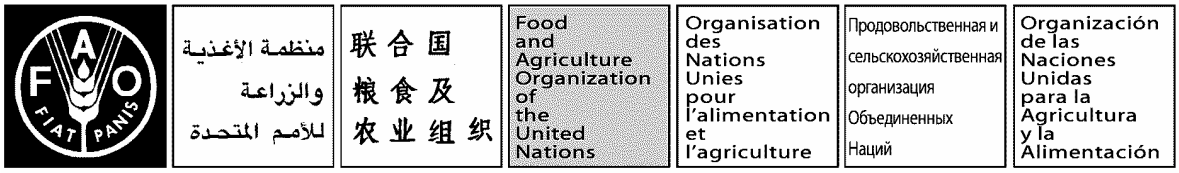
September 2009



COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

FRAMEWORK STUDY ON FOOD SECURITY AND ACCESS AND BENEFIT-SHARING FOR GENETIC RESOURCES FOR FOOD AND AGRICULTURE

This document has been prepared at the request of the Secretariat of the Commission on Genetic Resources for Food and Agriculture by the Centre of Excellence for Biodiversity Law (CEBLAW) (in particular by Gurdial Singh Nijar, *Director*, Gan Pei Fern, Lee Yin Harn and Chan Hui Yun) as a contribution to the cross-sectoral theme, *Consideration of policies and arrangements for access and benefit-sharing for genetic resources for food and agriculture*, which the Commission will consider at its Twelfth Regular Session.

The content of this document is entirely the responsibility of the authors, and does not necessarily represent the views of the FAO, or its Members.

TABLE OF CONTENTS

ABOUT THIS PUBLICATION

The Commission on Genetic Resources for Food and Agriculture (the Commission), at its Tenth Regular Session, recommended that the Food and Agriculture Organization of the United Nations (FAO) and the Commission contribute to further work on access and benefit-sharing, in order to ensure that it moves in a direction supportive of the special needs of the agricultural sector, in regard to all components of biological diversity of interest to food and agriculture.

At its Eleventh Regular Session, the Commission agreed on the importance of considering access and benefit-sharing in relation to all components of biodiversity for food and agriculture, and decided that work in this field should be an early task within its Multi-Year Programme of Work (MYPOW). Accordingly, the Commission decided to consider arrangements and policies for access and benefit-sharing for genetic resources for food and agriculture at its Twelfth Regular Session (19-23 October 2009). To facilitate discussions and debate on access and benefit-sharing for genetic resources for food and agriculture at the Twelfth Regular Session, the Secretariat of the Commission has commissioned several background study papers on use and exchange patterns of genetic resources in the different sectors of food and agriculture. The studies provide an overview of past, current and possible future use and exchange patterns, as well as a description of terms and modalities for use and exchange of animal, aquatic, forest, micro-organism genetic resources; and of biological control agents. Cross-sectoral studies have been commissioned to analyse use and exchange patterns in light of climate change and to review the extent to which policies and arrangements for access and benefit-sharing take into consideration the use and exchange of genetic resources for food and agriculture in particular, subject of the present background study paper.

The broad ranges of studies are intended to provide insight, necessary to maintain, establish and advance policies and arrangements for access and benefit-sharing for biodiversity for food and agriculture. The studies may also contribute to the negotiations of an International Regime on Access and Benefit-sharing in the Ad Hoc Open-ended Working Group on Access and Benefit-sharing under the Convention on Biological Diversity.

ACRONYMS AND ABBREVIATIONS

ABS: Access to genetic resources and benefit-sharing

CBD: Convention on Biological Diversity

CEBLAW: the Centre of Excellence for Biodiversity Law

CONAGEBIO: National Commission for the Management of Biodiversity of Costa Rica

EIA: Environmental impact assessment

EPA: Environmental Protection Agency

FAO: Food and Agriculture Organization of the UN

GRFA: Genetic resources for food and agriculture

ILCs: Indigenous and local communities

IPRs: Intellectual property rights

ITPGRFA: International Treaty on Plant Genetic Resources for Food and Agriculture

MATs: Mutually agreed terms

MTA: Material Transfer Agreement

NBA: National Biodiversity Authority of India

NCA: National Competent Authority

PBR: Plant Breeder's Rights

PGRFA: Plant genetic resources for food and agriculture

PIC: Prior informed consent

PVP: Plant Variety Protection

SMTA: Standard Material Transfer Agreement

TK: Traditional knowledge

UPOV: International Convention for the Protection of New Varieties of Plants

SUMMARY OF FINDINGS

This study shows that, by and large, the main thrust of the laws, guidelines and other arrangements on access to genetic resources and benefit-sharing (ABS) is to assert sovereignty of countries over their biological and genetic resources. The laws are thus replete with elaborate and comprehensive provisions on the various conditions relating to access with the aim of optimizing benefits. The preservation of the rights of indigenous and local communities (ILCs) seems mainly directed to seeking their prior informed consent (PIC) and to permitting the unimpeded use and exchange of genetic resources among the communities. Generally, apart from some rather vacuous general provisions, there seems to be a paucity of any dedicated provisions that specifically take into account the distinctive features of genetic resources for food and agriculture (GRFA), in particular the need to allow for their unimpeded use and exchange. Consequently, apart from the general power in a meagre handful of laws to assess applications for access, or to refuse access, on the ground of food security, the issue of food security remains to be addressed in a meaningful way.

What is equally plain, however, is that these laws and arrangements have significant potential implications for access to GRFA and food security. In this context, the following conclusions may be tentatively drawn:

1. The Focus of National ABS Laws

- The national ABS laws and other arrangements differ widely as to the range of resources they cover. Some seem to cover all resources in the widest possible sense. Others limit their scope to genetic resources strictu sensu.
- The coverage of ABS laws is relevant to the food and agriculture sector as it determines to what extent the sector will be affected by these laws.
- While a few laws seem to explicitly exclude agricultural commodities (which will include seeds, grains, livestock) from their scope, most ABS laws seem to cover the use of genetic resources for agricultural research and development.
- Very few instruments seem to distinguish between genetic resources for food and agriculture and other uses of genetic resources.
- Almost all countries include either explicitly or by implication both wild and domesticated sources of the genetic materials.
- Most national laws and other arrangements do not have specific provisions covering the use of genetic resources for breeding purposes.
- Most countries make special provision for genetic resources accessed for research purposes by either excluding such access from the scope of their laws; or by providing for facilitated access (such as by simplified procedures) for the research use of these resources. It was noted, however, that research in respect of food and agriculture typically and ultimately aims at commercial use and circulation of agricultural products. For this reason the research exemption of most ABS laws may be of very limited practical significance for food and agriculture.
- Nonetheless it was noted that ABS laws and other arrangements which do not provide for any research exemption or simplified procedure for access may ultimately restrict access to genetic resources more severely than even patent and plant variety protection (PVP) laws.

- While there is general recognition of the special position of ILCs as regards the use and exchange among themselves of genetic resources including that for GRFA, few laws exempt access to such resources by farmers or breeders.
- In some countries, access laws and arrangements may require access approval for activities which under the PVP laws of these countries do not require the permission of the proprietor of the plant variety. This reflects the policy of the country to allow exchange among farmers of seeds and to allow breeders to use protected varieties for production and marketing of new varieties. This policy appears to be negated if then access to the use of such resources is restricted by the country's ABS laws.
- Some countries exclude from the scope of their ABS law activities for conservation purposes including conservation for GRFA. However it is unclear what happens to the use of the material later. The practical significance of such an exclusion will depend upon whether materials benefiting from this provision may be used for agricultural research and development. If access for conservation activities is not exempted from ABS laws, then this may pose a significant hurdle in respect of an area which is of crucial importance for current and especially future development of GRFA.

2. Access and Benefit-Sharing

- If cumbersome procedures are put in place by national ABS laws and arrangements, this may discourage conservation activities in relation to GRFA. This is not only problematic for the food and agriculture sector but could ultimately undermine an essential objective of ABS legislation and policy which is the conservation and sustainable use of biodiversity.
- To the extent that ABS laws cover GRFA, the *conditions* under which these resources can be accessed and under which the *conditions* for benefit-sharing operate are without doubt relevant for food and agriculture.
- ABS schemes and arrangements which provide for a multilayered authorization procedure - such as where approval must be sought from several authorities, or where separate authorisation must be sought for research and for commercialization - would seem to overcomplicate ABS for GRFA, especially given that commercial use is usually intended from the very outset, and, especially where the potential commercial benefits are usually known and predictable. This would not, of course, apply where such benefits are difficult to evaluate for a variety of reasons nor where genetic resources involve novel traits (nutritionals, nutraceuticals) as the profits for these upon commercial utilization may be difficult to predict.
- In the ABS laws and arrangements of most countries several authorities are involved or consulted in the decision-making process. However, very few of the laws involve the authorities responsible for food and agriculture, such as the ministries or agencies for agriculture. This is surprising given that GRFA will be the genetic resource most frequently accessed. In the many countries, ministries dealing with the environment seem to be driving the process.
- Some ABS laws and arrangements require multiple permits involving several authorities. This, as is frequently pointed out in debates on ABS, does not contribute to more efficiency and effectiveness of the authorization process. The same applies to approvals for the food and agriculture sector.
- Simple authorization procedures are essential for every sector with a high number of accessions and clearly defined end-uses. For this reason, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) provides a Standard Material Transfer Agreement (SMTA) or standardized accession procedure for specific uses of a defined number of crops and forages.

This facilitates access because of the many accessions. It may hence be instructive to consider such standardized ABS arrangements for the whole range of GRFA. This may also require different standards and conditions for different GRFA as one size may not fit all situations and sectors.

- A number of countries distinguish between nationals and non-nationals in their ABS laws and arrangements. This differentiation in favour of nationals seems to be based on the need to promote and nurture domestic production and enhance food security. However, if there is a high degree of interdependence of a country for its GRFA it may not serve the country's interest if there is no reciprocal system of international exchange of such resources. Indeed, it may be detrimental to the country's long-term food security if such international exchanges are hampered by such restrictions against foreign seekers of genetic resources.
- A number of approval conditions for access require public participation. The approval by ILCs and other stakeholders as well as the environmental impact assessment (EIA) process is obviously of relevance and inspired by cases of access to GR other than for food and agriculture. However for access to GRFA a full blown public consultation and EIA may not be entirely appropriate as, generally, no real environment impact is involved when accessing and exchanging genetic resources from farmer's fields.
- Further, the imposition of administrative procedures and fees/rates in respect of access sought, adds to the bureaucracy and transaction costs and makes more difficult the free access, use and exchange of GRFA. Although the rationale for these administrative costs is to help ease the financial administrative burden on provider countries, this must be balanced against the need to minimize bureaucratic hurdles especially when the objective is to facilitate free use and exchange of GRFA to secure food security. Further, as developing countries too need, presently (as is evident in the case of livestock) and in the future, to access GRFA from other provider countries, they could face similar barriers if the same laws are applied to them.
- Where there are no timelines provided by the laws for the processing of applications for access, which was the position in most of the laws and arrangements, the free use and exchange of GRFA is unduly hampered. Lengthy approval process may also pose problems to a specific sector of food and agriculture which is the sector for biocontrol or biosecurity. There may be situations where the use of such measures is imperative when undue delay may have adverse effects for GRFA.
- As regards the time taken for negotiating benefit-sharing provisions, there may not be a need for lengthy procedures for GRFA because invariably it is clear what the parties want and what benefits there are to be shared. Some countries provide for phased agreements where the benefits are negotiated later when it becomes clear ('imminent') that a commercial product will result. Where the purpose and the benefits of the GRFA are clearly known from the outset, there may not be a need for such arrangements. Further, it bears reiteration that developing countries as present and future users of GRFA may face similar obstacles if the same requirements as to benefit-sharing are applied to them. Already there is extensive flow of animal germplasm from the countries of the North to those of the South.[1]
- With regard to monetary and non-monetary benefits, as in the case of access, the food and agriculture sector might benefit from standardized benefit-sharing provisions as appear in the

[1] The access of animal germplasm by the South from the North has been funded largely by public sector subsidies and through commercial market transactions. If the provider countries of the North were to impose similar requirements for access, especially as regards benefit-sharing, it is difficult to gauge the consequences on developing countries. Absent any public funding, it could impede the free flow and exchange of such genetic resources to these countries.

SMTA of the ITPGRFA, although probably there may be a need for sector specific arrangements for animal, fish, and other materials. Under the SMTA users of plant genetic resources for food and agriculture (PGRFA) who commercialise a product must pay 1.1% of the sales of the product (less 30%) if they do not make their product freely available for further research and breeding. The SMTA also foresees as an option, a discounted rate for access to GR of a specific crop where the recipient agrees to make payments based on the sale of his products belonging to the same crop independent of whether or not the product is available without restriction.

- Individual case-by-case benefit-sharing agreements may however, require more time and will usually come with added transaction costs. This appears to be particularly ill-suited in the case of PGRFA where there is a high degree of accessions.
- The benefits, as illustrated by an analysis of agreements entered into voluntarily and not on the basis of an ABS law, show that most of the benefits are non-monetary in nature, and that these may be more significant in reality.
- The imposition of requirements that every new use of a resource accessed must be separately applied for and/or the benefit-sharing terms renegotiated[2] may not be appropriate to GRFA where the use of the resource is known and does not change. Such restrictions could inhibit the free flow of genetic resources amongst traditional users and breeders, and thus have the potential to adversely impact the development of such resources.
- Elaborate procedures for transfer of the genetic resource from the person originally granted access to others, especially to bona fide researchers, breeders and developers tend to inhibit the free flow and exchange of GRFA and impede research and development.[3] Again the consequences of this requirement and the one in the preceding paragraph on developing countries as users accessing materials from other provider countries, needs to be carefully considered.
- None of the instruments appear to give an absolute right to access specific GRFA. The instruments provide a range of conditions that the applicant needs to meet. Although it appears that once met there is a right of access, yet there is no obligation on the part of the provider country to grant access. ABS arrangements are commercial in nature and only when both parties agree to the terms (such as the amount or kind of benefit-sharing) will access materialize. Further, the instruments of several countries provide numerous additional, and rather vague and broad, grounds on which access may be denied. This poses a further hurdle to the free access and exchange of GRFA.

3. Monitoring and Enforcement

A number of instruments have elaborate provisions requiring tracking and monitoring of the use of GRFA. Such tracking and monitoring can give rise to considerable difficulties and increase costs significantly. For this reason the Contracting Parties of the ITPGRFA explicitly agreed that the access to the Multilateral System shall be accorded ‘without the need to track individual accessions. (Art 12.3.b). Such minimal tracking and monitoring requirements in case of GRFA may be considered as a possible value contribution to research and development.

[2] The Bonn Guidelines state that permitted uses should be clearly stipulated and new application for changes or unforeseen uses should be required – Article 34.

[3] Bonn Guidelines suggest that special terms and conditions should be established under MAT to facilitate taxonomic research for non-commercial purposes in this context – Article 16(b)(viii).

I. INTRODUCTION

1. Background

1.1. Purpose of the study

The Centre of Excellence for Biodiversity Law (CEBLAW) has been engaged to prepare a framework study for the Food and Agriculture Organization of the United Nations (FAO) pursuant to a Letter of Agreement.

The study involved an analysis of existing national, regional and international legal and other instruments relating to access and benefit-sharing (ABS) of genetic resources for food and agriculture (GRFA). The study is designed to focus on those aspects and provisions in these instruments which may potentially impact on food security and agriculture, or are relevant to, or specifically address the special nature of GRFA and their distinctive features and problems.

1.2. Scope of the study

The study addressed the following:

1) An identification of the distinctive features of GRFA.

2) An identification of the problems peculiar to GRFA.

3) A survey of national, regional and international legal and non-legal instruments relating to access and benefit-sharing to ascertain the following:

   a. The kinds of genetic resources addressed.
   b. Whether there is a special focus on GRFA.
   c. Whether there are provisions, including exceptions and exemptions, that specifically take into account the special features of GRFA, or address issues which may be of relevance to the use and exchange of these resources.
   d. The nature of these provisions and, where such information is available, to what extent these provisions actually achieve the objectives of contributing directly or indirectly to food security.
   e. Whether and how the laws and regulations of Contracting Parties of the International Treaty on Plant Genetic resources for Food and Agriculture (ITPGRFA), in particular of those Parties which have adopted legislation on access and benefit-sharing, reflect the provisions of this Treaty.

Impact of these instruments on exchange and use of GRFA

Factors used to assess the potential implications, including on food security:

   a. Access requirements: an examination of the rules and procedures, including those relating to institutional arrangements, timelines, limitation of use of genetic resources, limitation on the transfer of the resource, procedure for PIC and MATs, and mechanisms and mode for MATs.
   b. Benefit-sharing provisions and whether they foster or hinder food security, including their impact on research and development.
   c. Provisions relating to Traditional Knowledge (TK) associated with GRFA and their impact on food security.

1.3. Countries examined

The study analyzed the laws, policies and other instruments of several countries and regions. These were chosen to give a fair representation of the range of laws and guidelines that have been enacted in the world. Included in the study were the laws and guidelines of developing countries from Asia, Africa, Latin America and Central America; as well as those developed countries, such as Australia and the state of Hawaii of the United States of America (USA). Also included in the survey were relevant international and regional frameworks and guidelines. The regional guidelines were selected as they inform the laws and policies of countries that make up the region. This was the case especially with the regional laws of the Latin American countries that make up the Andean Pact countries and the Model African law. The international guidelines, in particular the Bonn Guidelines, were developed to assist in putting into operation the access and benefit-sharing provisions of the Convention on Biological Diversity (CBD), have been the basis upon which several countries have shaped their ABS laws and policies.[4]

The full list of the countries and their regions examined in this study can be found in Appendix I.

1.4. Methodology

The study is based on an analysis of the laws, guidelines, and in some cases reports by governments to relevant international bodies (primarily the Convention on Biological Diversity). The full list of these legal instruments can be found in Appendix II. There was no investigation of how these laws and guidelines work in practice; nor indeed of the level of implementation of these laws and guidelines by national authorities. Thus this study does not explore, nor does it intend to make any statement about the actual impact in practice of the provisions examined.

1.5. Disclaimer

Whilst care was taken to examine and analyze the provisions of each of the laws and other instruments relating to access and benefit-sharing of genetic resources of each country selected, it was not possible to examine the entire corpus of laws of these countries that may relate to access and benefit-sharing. Nor was it possible to locate the particular law and provision in the context of the laws of each country or its legal system. This was especially the case where matters affecting GRFA were spread over a large number of sectoral laws. It is indeed a formidable task to trace the existence of these laws in other sectors, more particularly because the connection with ABS is often rather tenuous or indirect. This is further complicated by the fact that there seems to be no common definition of what constitutes an ABS law or measure. The upshot is that only the laws directly described as an ABS law or measure are examined and analyzed.

There is yet another difficulty presented by the fact that there is no common understanding of some of the complicated issues and terms. This is further exacerbated by the fact that some of the original legal texts were translated into English.

[4] The first draft of the Guidelines was prepared in Bonn in October 2001. It was adopted with some changes by the Conference of the Parties to the CBD at its sixth meeting in April 2002. The guidelines are intended to help Parties, Governments and other stakeholders when establishing legislative, administrative or policy measures on access and benefit-sharing and/or when negotiating contractual arrangements for access and benefit-sharing: see further Introduction to the Bonn Guidelines on Access to Genetic resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation, Secretariat of the CBD, 2002, at p. III.

2. Access to genetic resources for food and agriculture

The major crop, animal and aquatic genetic resources, together with many other genetic resources, form the foundation of the world's food basket. These resources are the result of the collective breeding efforts of farmers, herders, pastoralists, fishing communities and others over millennia. These communities managed, conserved and improved GRFA. This was possible only in a context in which there was free and ready access to these resources and, more importantly, resources were freely exchanged. The resilience of the available present day food diversity reflects the cumulative genius of all those who directly and indirectly contributed to overcoming environmental and agricultural challenges. Globally genetic resources remain essential to achieving food security and ensuring sustainable livelihoods, especially, in poorer and marginal areas of the world.

A new international legal architecture has emerged that may be redefining the basis for the flow of GRFA. The Convention on Biological Diversity (CBD) provides an impetus for this change. Enacted in 1992, the CBD 'reaffirmed' the sovereignty of countries over their natural resources. Parties to the Convention have obligations regarding the right to determine the conditions upon which their resources could be accessed. One of the three key obligations of the CBD is that Parties must implement through their national laws or policies, is access and benefit-sharing (ABS) – the granting of access to genetic resources and benefit-sharing arising out of the utilization of these resources within their jurisdiction through bilaterally negotiated contracts on the basis of mutually agreed terms (MATs) and prior informed consent (PIC). Further, presently there are negotiations under the CBD, initiated in 2004, to develop an international regime on ABS to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources in line with the Bonn Guidelines. The ultimate scope of the international regime, in particular in relation to GRFA and any impacts is still unclear at this stage of the negotiations. ABS provisions may have an impact on the use and exchange of GRFA in a way that may be entirely different from, and in fact more severe than, their impact on the use and exchange of genetic resources for other purposes.

The Multilateral System ushered in by the International Treaty on PGRFA[5] created a Multilateral System of access and benefit-sharing for those plant genetic resources that are of major importance for food security and on which countries are highly interdependent. Those resources, mentioned in Annex I of the International Treaty on PGRFA, are freely exchanged against minimal costs on the condition that benefits must be shared in case the resource is commercialized, thus establishing a plant genetic resources commons. Thus, the Treaty creates a common pool from which genetic resources may be taken on standard conditions, including benefit-sharing arrangements. This reduces dramatically the transaction costs that will otherwise be incurred in bilateral negotiations over the extensive individual accessions. It also overcomes the difficulty of establishing the country of origin of the resource. Further, the rise of patent protection over innovations in the field of PGRFA has tended to restrict the availability of PGRFA for further research and breeding. The Multilateral System limits the extent to which intellectual property rights (IPRs) can be taken out within the Multilateral System and provides for enhanced benefit-sharing where such restriction occurs.

These advantages underline the need to consider the Treaty model as a possible desirable alternative to bilateral ABS arrangements, especially since these may disadvantage large numbers of people who exist

[5] The Treaty was adopted by the UN Food and Agricultural Organisation (FAO) Conference in 2001 and entered into force in 2001.

outside the market system and have no means to gain meaningful entry to it.[6] These aspects merit serious consideration in the development of any ABS laws whether at the national or international level.

3. The special nature of genetic resources for food and agriculture (GRFA)

The special nature of GRFA is widely acknowledged. The Conference of Parties of the CBD recognize "the special nature of agricultural biodiversity, its distinctive features, and problems needing distinctive solutions".[78]

These distinctive features were identified to include the following:[7]

- Its central role to satisfy basic human needs for food and livelihood security;
- The recognition that it is managed by farmers and that the many components of agricultural biodiversity depend on this human influence; as well as the fact that indigenous knowledge and culture are integral parts of the management of agricultural biodiversity;
- An acknowledgement that there is a great interdependence between countries for the GRFA;
- An increasing awareness that for crops and domestic animals, diversity within species is at least as important as diversity between species and has been greatly expanded through agriculture;
- The understanding that because of the degree of human management of agricultural biodiversity, its conservation in production systems is inherently linked to sustainable use;
- The recognition of the reality that, nonetheless, much agriculture biodiversity is now conserved ex situ in gene banks or breeders' materials;
- The realization that the interaction between the environment, genetic resources and management practices that occurs in situ within agro-ecosystems often contributes to maintaining a dynamic portfolio of agriculture biodiversity.

4. An Elaboration - the need for free flow of genetic resources

Many GRFA, in particular plant and animal genetic resources, have been developed over many centuries on the basis of free exchange.8 The domestication of crops and farm livestock required a sustained and continued process of selection. The resources could be imbued with new traits, including specific desirable qualities to improved taste, colour or smell of products. Also, unfavourable traits could be reduced or eliminated. Genetic resources could also help to overcome specific environmental and biological conditions that limit agriculture productions, such as droughts or pest outbreaks.9 Central to this was the access to, and free exchange of, a broad and diverse range of genetic resources. To address ever changing consumer demands and production conditions, exchange needs to be continuous and will

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[6] Michael Halewood and Kent Nnadozie, 'Giving Priority to the Commons: The ITPGRFA' in Geoff Tansy and Tasmin Rajotte, *The Future Control of Food,* Earthscan, 2008, p. 115 at p. 139.

[7] Appendix to CBD/COP DECISION V/5.

[8] Historically, plant species moved freely between Europe and the colonies. This brought the tomato to Italy, maize to Africa, wheat to Latin America and the potato to Ireland: Rebecca Margulies, Note: Protecting biodiversity: recognizing intellectual property rights in plant genetic resources, *Mich. J.Int'l Law*, (1993) 14: 322-356. See further: Kloppenburg, Jack R. Jr., *First the Seed: The Political Economy of Plant Biotechnology 1492-2000,C*ambridge University Press, UK, 1988, pp. 153-157.

[9] *'Maintaining animal genetic diversity will allow future generations to select stocks or develop new breeders to cope with emerging issues, such as climate change, diseases and changing socioeconomic factors'*: Jose Esquinas-Alcazar, the Commission on Genetic Resources for Food and Agriculture, cited in Geoff tansy and Tasmin Rajotte, *The Future Control of Food,* Earthscan, 2008, p. 138.

often involve successive generations of farmers and breeders, as the resource developed by predecessors forms the basis for subsequent crop and animal development and improvement. Additionally, the resource had to be managed so that the genetic resources developed remained stable. For this, too, the free flow of the genetic resources among farming and agriculture-based communities was crucial.

Thus, a crucial feature of GRFA is the need for unimpeded access by farmers and other traditional breeders to shared genetic resources; and as a sub-set, the ability to exchange the resources freely among themselves.

There is also an ever increasing demand for access to a wider range of plant, animal and other GRFA for the following ends:

- The production of new varieties and breeds that are economically and environmentally sustainable that will use cheaper and less harmful inputs;
- The development of new varieties and breeds suited to the needs of farmers in marginal lands or economies; and
- The development of new varieties and breeds that incorporate increased genetic diversity.

5. Countries' interdependence

Production of a crop variety often requires material from many farmers and the input of a broad range of genetic resources, often from a range of countries. Even for the production of commercial varieties a large number of samples may need to be screened. It has been suggested, for example, that in the case of plants, as many as 60 different landraces from 20 – 30 countries may be used.[10] As regards animal breeds, the approximately 40 subsisting domesticated animal species were spread around the world following patterns of human migration, trade exploration and colonisation. Breeds of many species resulting from distinct domestication were brought together and mixed in later years.[11] This incredible mix of parentage also typifies the conditions of traditional small scale farming practice with regard to the exchange of genetic materials.

There is thus, an incredible level of interdependence of countries and farming communities in the use and development of genetic resources for food and agriculture. The degree of dependence on PGRFA for most regions has been estimated to be as high as over 50%.[12] In Central Africa with respect to PGRFA it ranges from about 70% to 94%. With the Indian Ocean countries, it ranges from 85% to 100%. Significantly no country was considered completely self-sufficient. The same position seems to obtain in the case of global flows of livestock germplasm, although there is relatively little information. Hence the vital need to facilitate the continued access and exchange and further development of these resources without unnecessary barriers is clear, as is the need to ensure that benefits resulting from the use of shared genetic

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[10] Gerald Moore & Witold Tymowski, *Explanatory Guide to the ITPGRFA*, IUCN Environmental Policy and Law Paper No 57, IUCN-ELP, 2005, at p. 3. See also Graham Dutfield, *IPRs and the Life Sciences Industries,* Ashgate, 2003, at pp. 176-177. This incredible mix of parentage presents practical difficulties in ascertaining the country of origin of the products of plant breeding, and to some lesser extent, the country where it acquired its distinctive properties, especially which particular genetic input actually produced that distinctiveness.

[11] SGRP, Policy Briefing, *Farm Animal Resources: Technical Considerations for Policy-Makers concerning Conservation and Use,* at p. 2. A particularly illustrative example is given. All indigenous chicken from Europe, Africa, Melanesia, Japan, Korea, North, South and Central America were originally introduced from South and/or SE Asia.

[12] Study presented to the FAO CGRFA: Ximena Flores Palacio, *Contribution to the Estimation of Countries' Interdependence in the Area of PGR*, CGRFA, Background Study Paper No. 7 Rev.1.

resources reaches farmers, pastoralists, breeders, consumers and society as a whole.[13] This will enable continued crop and breed improvement, and is thus, critical to modern agriculture. World food security ultimately depends on this improvement, especially since plant products contribute as well to the vast proportion of the world's human energy needs, especially for developing countries.[14] Farm animals also play crucial roles in food security, improving nutrition and in rural development.

6. Use and exchange as means to prevent genetic erosion

The continued exchange and use of GRFA are important to prevent the loss of genetic diversity. Many GRFA are different from many other resources in that it is their continued use and exchange which helps to preserve their existence. Short-term country planning pressures are resulting in globalization of livestock markets, with ownership concentrated in large agribusiness conglomerates. This has been identified by FAO as the largest single factor negatively affecting farm animal diversity. The specialized breeds of modern agriculture to optimize specific desirable production traits depends on high external inputs and is fast eclipsing traditional production systems, which require access to multi-purpose animals. The risk of extinction is reaching alarming proportions. Around 20% of animal breeds are at risk. One breed is lost every month. Of the more than 7,600 breeds in the FAO's global database of farm animal genetic resources, 190 have become extinct in the past 15 years with another 1,500 at further risk.[15] Much the same happened in respect of plant genetic resources. The push towards commercially mass-produced varieties was at the expense of diverse land races. This characterized the Green revolution. Its effects and particularly the problem of crop uniformity were felt in the 1970s with the corn blight in the US.[16]

It is readily apparent that any denial, or limitation, of access to these resources could potentially have adverse effects on the food security for countries.[17] On the other hand, unlimited access also has a history of perpetuating inequities. Farmers and breeders gave ready access to the genetic resources developed over time. It represented their cumulative genius in developing new, diverse and resilient varieties based on their traditional and customary practices – in essence ongoing *in situ* 'research' in their fields. These innovations – seeds, germplasm, genetic resources of animal and aquatic origin - found their way to international research centres. Commercial interests accessed these for free and turned them into products for profit. The claim of exclusive patent monopoly rights over these accessed material exacerbated the inequity. Soon there were strident voices decrying this lack of balance, especially the ownership claims over products derived from the traditional knowledge of indigenous peoples and of farmers and breeders, especially from developing countries. The term 'biopiracy' entered the vocabulary to describe this unfair and unethical usurpation.

There was an attempt to resolve these problems in the context of the FAO. But it yielded minimal results – the recognition of the contribution of the traditional farmer in developing the plant. But the right was not vested in the individual farmer. Instead it accrued to the farmers' governments to receive assistance in

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[13] Jose Esquinas-Alcazar, Secretary General FAO's Commission on Genetic Resources for Food and Agriculture, cited in Geoff Tansy and Tasmin Rajotte, *The Future Control of Food,* Earthscan, 2008, pp. 138.

[14] Study prepared by the Nutritional Division of FAO, Background Study Paper No.11, April 2001.

[15] FAO's Final Report on the State of the World's Animal Genetic Resources, document CGRFA-11/07/Inf.6 at www.fao.org/ag/cgrfa/cgrfa11.htm.

[16] The epidemics of the 1970s led to missions to collect germplasms and to establish gene banks. The Consultative Group on International Agricultural Research (CGIAR) was born out of this initiative and supports a network of 16 international research centres. The CGIAR conserves approximately 600,000 seed samples, that is about 40% of the world's unique germplasm in storage worldwide.

[17] For example, 70% of the world's rural poor depend on livestock as a critical component of their livelihoods.LID, *Livestock in Poverty-focused Development,* Livestock in Development, Crewkerne, UK, 1999, cited in [17] SGRP, Policy Briefing, *Farm Animal Resources: Technical Considerations for Policy-Makers concerning Conservation and Use,* at p. 1.

the maintenance of genetic resources. It was essentially a general obligation of the North to help the South, tied into the context of aid and dependency. An international gene fund, administered by FAO for the conservation and utilisation of plant genetic resources, was set up to concretise these rights. However, the fund did not materialise because of a lack of contributions from Northern corporations and their governments.[18]

An exponential increase in the ownership through patents and other protection regimes of plants, breeding materials, genes and their progeny, has raised a whole new order of challenges. The position is exacerbated by the broad IPR claims over what are in fact products of nature; and, as well, the concentration of IPRs in a small coterie of large global companies. There is increasing convergence and consolidation of such companies in the past decade. Forty-nine percent of the seed market is controlled by just 10 companies. They account for 55% of the commercial seed market and 64% of the patented seed market.[19]

These developments provided the impetus for the emergence of the CBD. The Convention represents the success of developing countries to address this inequity. It reasserts the sovereignty of countries over their biological resources, imposes a requirement for the prior informed consent (PIC) of these countries for access to their genetic resources and makes mandatory the fair and equitable sharing of benefits if there is any commercial and other utilization arising out of the use of these resources. Significantly, the CBD also obliges Parties to cooperate to ensure that IPRs do not undermine the Convention's objectives.[20]

The ITPGRFA – establishing a multilateral system for exchange of plant genetic resources for food and agriculture (PGRFA) – was a direct outcome of the attempt to restore some balance. Significantly, as well, the Treaty prohibits recipients of the genetic resources from the system from claiming IPRs that will limit the facilitated access to the PGRFA or their genetic parts or components in the form received.[21] The establishment of a process by the COP of the CBD in 2004 to negotiate an International regime on ABS[22] reflects the culmination of efforts directed primarily by developing countries to provide for an international framework to ensure that fair and equitable benefits accrue to them as a quid pro quo for granting access to their genetic resources. This came about as a result of the concerted initiative by developing countries at the World Summit. The Summit, as part of the mandate of the Plan of Implementation of the World Summit on Sustainable Development for Action, directed the negotiation 'within the framework of the CBD an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources'.[23]

7. ABS for PGRFA: multilateral or bilateral?

Although generally the CBD is thought to contemplate bilateral arrangements for ABS, there is nothing in the language of the CBD to eschew the implementation of its provisions by a multilateral or regional mechanism. The point is made in the context of the importance of the interdependence of the global community for the use and development of the resources, the need for free and uninhibited use and exchange; and as well the difficulty of determining, in respect of domesticated resources, not only the country of origin but also where it acquired its distinctive property or properties. It may be noted, on the

[18] Gurdial S Nijar, *In Defence of Local Community Knowledge and Biodiversity*, TWN, paper 1, 1996, p. 8.

[19] Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: trends in partnerships across sectors,* CBD Technical Series No. 38, CBD, UNEP, 2008 at pp. 15-16.

[20] Article 16.5, CBD.

[21] Article 12.3(d).

[22] Decision VII/19.

[23] Paragraph 44(o).

other hand, that despite the compelling arguments to include all food crops in its multilateral system of exchange - with its automatic PIC by members and standardized MTAs for ABS - yet the ITPGRFA does not do so. This implies the real difficulty of securing universal agreement for a multilateral ABS system for all genetic resources. Secondly, although the IR could be more useful for ABS in such fields as pharmaceutical bioprospecting – where continuous free and unimpeded use and exchange forms no part of the genetic resources accessed – yet examples abound where genetic resources for food and agriculture are the subject of bilateral ABS arrangements. For example, as recently as 2006 Ethiopia concluded an agreement with a Dutch company on the exclusive access to an agreed list of *Teff* varieties to be used for producing flour and bread mix and gluten-free beverage products and to develop new varieties of the plant more suitable for producing such products. Another similar ABS agreement was entered into between Ethiopia and a UK company with regard to *veronica* – an oilseed crop.[24] The Swiss Academy of Sciences also lists several research case studies involving the collection and transfer of genetic material related to food and agriculture;[25] and suggests how ABS measures may be implemented in practice.[26]

As these bilateral arrangements proliferate, countries may be even less willing to give up on bilateral ABS arrangements especially as they anticipate benefits from them.

[24] See further, Gurdial S Nijar, 'Legal Issues and Frameworks relating to National and ASEAN ABS of Biological Resources: current trends and future needs', in Shukor et al (eds), *Agrobiodiversity in Malaysia,* Malaysian Agricultural research and Development Institute (MARDI), 2008, 150 at pp. 165/166.

[25] Need for collection from Togo and Benin (in West Africa) of fungi that is an antagonist to the pests destroying the yam – the second most important tuber crop in West Africa. Also may require the collection of the yam plant – which is listed in the multilateral system under the ITPGRFA. The project is a collaboration between a Swiss Research Institute and the International Institute of Tropical Agriculture in Benin.

[26] Swiss Academy of Sciences, *ABS: Good Practice for Academic Research on Genetic Resources,* 2006, 14.

II. THE NATURE OF THE NATIONAL LAWS DEALING WITH ABS

For many countries, provisions regulating access to genetic resources and benefit-sharing are spread over a plethora of laws, regulations and guidelines. These countries include: **Guyana,**[27] **India,**[28] **Uganda,**[29] **Costa Rica**,[30] **Kenya**,[31] **Philippines**,[32] **South Africa**,[33] **Australia**,[34] and **Malawi**.[35]

Other countries have adopted ABS national and sub-national measures in detail in a single specific act. Of these, some have enacted legislation dealing solely and directly with ABS: **Brazil,**[36] **state of Sabah (Malaysia),**[37] **Queensland (Australia),**[38] **Northern Territory (Australia),**[39] **Ethiopia**[40] **and Bolivia.**[41]

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[27] Environmental Protection Act 1996 (has no express provisions on access), 'Guyana Environmental Act 1996', the draft Environmental Protection (Bio-prospecting) Regulations 2001 (regulates access for purposes of bioprospecting), 'Guyana Draft Regulations 2001', and the Guidelines for Biodiversity Research issued by the EPA (as the Regulations have yet to come into force) 'Guyana Guidelines for Biodiversity Research'.

[28] The National Policy and Macro-level Action Strategy on Biodiversity 1999 (to consolidate and augment existing strategies and programmes relating to biodiversity), Biological Diversity Act 2002, 'Indian Biodiversity Act 2002' , Biological Diversity Rules 2004, 'Indian Biodiversity Rules 2004' (both regulates access to biological resources and associated TK and benefit-sharing in detail) and the Guidelines for International Collaboration Research Projects Involving Transfer or Exchange of Biological Resources or Information 2006, 'Indian Guidelines for Collaboration Research Projects 2006'.

[29] National Environment Act 1995, 'Uganda Environmental Act 1995' gives the basis for Access and Benefit -Sharing in Uganda, together with the National Environment (Access to Genetic Resources and Benefit-sharing) Regulations 2005, 'Uganda ABS Regulations 2005'.

[30] Biodiversity Law 1998, 'Costa Rican Biodiversity Law 1998'; The General Rules for the Access to the Genetic and Biochemical Elements and Resources of the Biodiversity 2003, 'Costa Rican Rules for Access 2003'.

[31] Environmental Management and Co-ordination Act 1999, 'Kenyan Environmental Act 1999' (no detailed measures on access and benefit-sharing) and the Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit-Sharing) Regulations 2006, 'Kenyan ABS Regulations 2006' (regulates access to genetic resources in Kenya for purposes of research, bio-prospecting, conservation, industrial application and commercial use).

[32] Wildlife Resources Conservation and Protection Act 2001(Republic Act No. 9147), 'Philippines Wildlife Act 2001' (general provisions regulating access to biological and genetic resources for the purpose of bioprospecting as well as non-commercial scientific research), Joint DENR-DA-PCSD Administrative Order #01 2004 *Joint Implementing Rules and Regulations Pursuant to Republic Act No. 9147,* 'Philippines IRR 2004' (general provisions regulating access to biological and genetic resources for the purpose of bioprospecting and detailed provisions regulating access for the purpose of non-commercial scientific research) and the Joint DENR-DA-PCSD-NCIP Administrative Order #1 *Guidelines for Bioprospecting Activities in the Philippines 2005*, 'Philippines Guidelines for Bioprospecting 2005' (detailed provisions regulating access to biological and genetic resources for the purpose of bioprospecting).

[33] Biodiversity Act 2004, 'South African Biodiversity Act 2004' (regulates access to indigenous biological resources for the purpose of bioprospecting and research other than bioprospecting) and Bio-prospecting, Access and Benefit-Sharing Regulations 2008, 'South African ABS Regulations 2008' (detailed provisions regulating bioprospecting, bioprospecting and export permits and benefit-sharing).

[34] Environment Protection & Biodiversity Conservation Act 1999, 'Australian Environment Act 1999', Environment Protection & Biodiversity Conservation Regulations 2000 & 2005, 'Australian Environment Regulations 2005', the Nationally Consistent Approach For Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources.

[35] Environment Management Act 1996, 'Malawi Environment Act 1996', Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi, 'Malawi Guidelines for Access'.

[36] Brazilian Provisional Act 2001 No.2, 186-16, 'Brazilian Provisional Act 2001'.

[37] Sabah Biodiversity Enactment 2000.

[38] Queensland Biodiscovery Act 2004.

[39] Biological Resources Act 2006, 'Northern Territory Act'.

[40] Ethiopian Proclamation to Provide for Access to Genetic Resources and Community Knowledge and Community Right, 2006, 'Ethiopian Proclamation 2006'.

[41] Bolivian Supreme Decree Nº 24676, Regulation of Decision 391 Common Access Regime to Genetic Resources 1997, 'Bolivian Regulations on Access 1997'. Bolivia is also bound by **Andean Decision 391**.

Others have general biodiversity laws which contain detailed ABS measures: **Vanuatu**,[42] **Bhutan**[43] **and Bangladesh**.[44]

Some countries have provided for ABS in general terms in a single piece of environment-related legislation: **Gambia**,[45] **Nigeria**[46] and **Afghanistan**.[47] Some have developed draft ABS measures: **Pakistan**[48] and the state of **Hawaii.**[49]

The web page of the CBD, which requires countries to report when its laws have been operationalized, shows that only 15 countries have notified the Secretariat of the existence of their national competent authority (NCA) on ABS as at May 1st 2009.[50] This implies that it is these countries that have implemented ABS laws, or are in the process of doing so. However, 10 of these countries (68%) have no ABS law. At the same time, there are countries that have not notified the CBD of the establishment of a NCA but are known to have an ABS law with implementation institutions and procedures. Whatever the case, it appears that very few countries have a fully operational ABS regime. This seems to be corroborated by the fact that there seem to be very few ABS agreements negotiated under a national ABS law or other measures.

This raises the question as to what impels these countries to introduce ABS laws when there are no steps taken to implement them. Some tentative reasons may be suggested. First of course is the salutary effect of the CBD. Some Contracting Parties take their political commitment seriously and no doubt feel obliged to put in place such laws or policies as required by the CBD. The CBD represents to them a hard-won victory in establishing their sovereign rights over their own biological resources with authority to determine access to genetic resources under their jurisdiction. Secondly, and more importantly, countries seem to be asserting sovereignty over their resources in anticipation of potential (large) benefits to be reaped in the future. This probably also explains why the scope of the laws is wide to maximize both the range of resources as well as activities in relation to the resource. Further, and as we discuss later, most laws include the regulation of both wild and domesticated resources, either expressly or impliedly.

This has implications for GRFA as most of these resources are domesticated. However, the fact that the ABS laws may create barriers with implications for GRFA and food security is not adverted to or addressed. Nor the fact that in respect of some resources (such as animal genetic resources), there is extensive movements of livestock germplasm from developed to developing countries. This could create problems of access for developing countries, including increased costs, if similar non-facilitative ABS laws were implemented in these countries.[51] Thirdly, the focus of many capacity building initiatives under

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[42] Environmental Management & Conservation Act 2003 (regulates access for bioprospecting), 'Vanuatu Environmental Act 2003'.

[43] Bhutan Biodiversity Act 2003.

[44] Biodiversity and Community Knowledge Protection Act of Bangladesh dated 29/09/1998, 'Bangladesh Biodiversity Act 1998'.

[45] National Environment Management Act 1994, 'Gambian Environment Act 1994'.

[46] National Park Service Decree 1999, 'Nigerian National Park Decree 1999' (regulates the prospecting of genetic material in and the removal of biological material from a National Park).

[47] Environment Act 2005, 'Afghanistan Environment Act 2005'.

[48] Draft law on Access and Community Rights: Legislation on Access to Biological Resources and Community Rights 2004, 'Pakistan Draft Law on Access 2004'.

[49] Draft Bill relating to Bioprospecting 2007. (The Bill requires the department of land and natural resources to adopt administrative rules, establishing requirements for obtaining a permit to conduct bioprospecting activities), 'Hawaiian Draft Bill on Bioprospecting 2007'.

[50] There seems to be widespread frustration within industry at the lack of clear NCAs to grant PICs: ibid at p. 24.

[51] These have been in the form of highly specialized breeds (live animals and/or semen to be used in cross-breeding. The costs have usually been subsidized by public-sector funding.

the CBD, especially for developing countries and countries in transition, has been assistance to formulate ABS laws. Finally, there is also the influence of fairly sustained regional initiatives such as by the Andean Pact group of countries of Latin America, by countries of the Organisation of African Unity and by the ASEAN group of countries. The explanation for the lack of follow up implementation measures may be either the loss of interest once the often external capacity building exercise is over; or, more importantly, because of the difficulty, and the time it takes to establish implementation mechanisms and institutions. This is probably linked to a lack of capacity.

1. The objectives of ABS laws and guidelines

There was a whole range of objectives that countries included in their ABS laws or measures. These included to:

- ensure the fair and equitable distribution of benefits derived from genetic resources;[52]
- ensure that biological resources are utilized in an effective and equitable manner in order to strengthen the food security of the nation;[53]
- protect TK associated with the resources, including the rights of local and indigenous communities;[54]
- recognize and protect farmers' and/or breeder's rights;[55]
- protect biodiversity;[56]
- ensure the conservation and sustainable use of genetic resources or biodiversity;[57]
- regulate access to genetic/biological resources;[58]
- facilitate access to genetic/biological resources;[59] and

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[52] Bonn Guidelines (although some of the objectives are more in the nature of guiding member states to achieve certain objectives in their law), **Bhutan**, **Costa Rica, Pakistan, Ethiopia, Australia**, **Andean Decision 391**, **ASEAN Framework Agreement** (to set minimum standards among the Parties), **Bangladesh**, the Australian state of **Queensland** (the benefits of biodiscovery), **African Model Laws, Uganda, South Africa**.

[53] **Bonn Guidelines**, **African Model Law**.

[54] **Bonn Guidelines** and **Bhutan** (also include innovation and practices of local communities), **ASEAN Framework Agreement, Australia** (recognize the special knowledge held by indigenous persons about biological resources), **Bangladesh** (to protect biological and genetic resources and the related knowledge, culture and practice from pollution, destruction and erosion). **Pakistan** (to project and support the rights of local communities over biological resources and their knowledge, innovations and practices), **Bangladesh** (to protect the sovereign rights of the Communities that have knowledge of biodiversity, and have managed, maintained, conserved, reproduced and enhanced biodiversity, genetic resources and traditional knowledge, culture and various forms of practice related to these resources and which are always held in common, to ensure participation and agreement of concerned communities in making decisions regarding the distribution of benefits), **African Model Laws**.

[55] **Bhutan, African Model Law** (farmers' rights and ensuring that women are also involved in decision making).

[56] **Bangladesh.**

[57] **Bonn Guidelines**, **Bhutan, Costa Rica, Malawi, Pakistan, Uganda, , ASEAN Framework Agreement, Bulgaria, Australia,** the Australian state of **Northern Territory, Afghanistan, Ethiopia, Bangladesh,** the Australian state of **Queensland** (by ensuring biodiscovery enhances knowledge of the State's biological diversity), **African Model Law** (with a particular focus on the major role women play).

[58] **Bhutan, Costa Rica, Pakistan** (to promote appropriate system of access), **Hawaii** (define bioprospecting; establish a permanently funded commission on prospecting and requirements for obtaining a permit to conduct bioprospecting activities), **Uganda** (to prescribe the procedure for access), **ASEAN Framework Agreement** (to set minimum conditions), **Australia** (establish an access regime designed to provide certainty, and minimise administrative cost, for people seeking access to biological resources), **Bangladesh, South Africa, African Model Laws.**

- promote technology transfer and capacity building.[60]

A vast majority of the countries stated explicitly the objectives of their ABS laws or arrangements. Further, most had cumulative[61] objectives. There are also other objectives identified by the laws and regulations of the countries.[62] It is noteworthy that only one regional model law referred explicitly to the purpose as ensuring that the biological resources are utilized to strengthen the food security of the nation.[63] One other proposed draft regional law declares as a principle, the importance of facilitating the exchange and utilisation of food crop germplasm to ensure that food security is enhanced.[64] However, the general intent of both these regional laws do not seem to have been effectively translated in the member countries of the region as yet so as to provide for easy access to GRFA for farmers, pastoralists and other communities.[65] It appears that farmers or other breeder communities wishing to access GRFA would be obliged, like all other applicants, to go through the process of obtaining PIC to access the resource.

Subsistence and marginalized farming communities would find it particularly difficult to do so, unless they are organized, the process for gaining access greatly simplified or governmental assistance is proffered in completing the process. In any event, the access requirements would be a barrier to the free use and exchange of genetic resources and further impede the ability to access, utilize and improve GRFA with potential adverse consequences for food security.

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[59] **Bonn Guidelines** ((provide a transparent framework to) ; also with particular reference to Taxonomic research, as specified in the Global Taxonomy Initiative), **Bhutan, Costa Rica, ASEAN Framework Agreement** (between the Parties and to also encourage the sharing of resources, technologies, experiences and information), the Australia state of **Queensland** (to facilitate access by biodiscovery entities to minimal quantities of native biological resources on or in State land or Queensland waters for biodiscovery), the Australian state of **Northern Territory** (to facilitate bioprospecting).

[60] Bonn Guidelines, Bhutan (at the national and local levels, including the building of scientific and technological capacity relevant to the conservation and sustainable use of biological diversity), Costa Rica (To assure and facilitate access the access to technologies and their adequate, effective and selective transference, under fair, favorable and mutually agreed conditions so that the national capacity be improved), Andean Decision 391 (To promote the consolidation and development of scientific, technological and technical capacities at the local, national and subregional levels), Bangladesh (to promote and encourage the building of national scientific and technological capacity relevant to the conservation and sustainable utilization of biological and genetic resources), African Model Law (promote and encourage the building of national and grassroots scientific and technological capacity).

[61] See for example: **ASEAN Framework Agreement 2004, Andean Decision 391, Costa Rica, Pakistan, Uganda, Hawaii.**

[62] To prevent illegal access to genetic and biochemical resources and associated Traditional Knowledge; to make plant varieties subject to property rights; to ensure that plant breeders are able to recover the cost from useful improvements and innovations, and continue to do so; to provide legal recognition of varieties which are not protectable under the internationally existing patent and/or plant breeders rights laws and thereby recognize farmers' plant variety improvements and innovations and provide a means of sharing benefits derived from the use of farmers' or traditional varieties as breeding material for commercial purposes; to promote access to foreign sources of improved plant varieties to farmers: **Bhutan**; to ensure that research of genetic materials does not lead to loss of biological diversity; to ensure that exchange of genetic resources germplasm and commercialization of research results are done in such a way that Malawi benefits economically from whatever is exported: **Malawi**; to foster and protect the *sui generis* communitarian intellectual property rights: **Costa Rica**; to establish ownership of biological resources: Hawaii; to lay the foundations for the recognition and valuation of the genetic resources and their by-products and of their associated intangible components, especially when native, Afro-American or local communities are involved: **Andean Decision 391**; to promote new innovations and discoveries to reproduce, manage and enhance biodiversity and genetic resources: **Bangladesh**; to promote the supply of good quality seed/planting material to farmers: **African Model Law**; to promote awareness on implementation of relevant provisions of the Convention on Biological Diversity: **Bonn Guidelines**.

[63] **African Model Law.**

[64] Proposed draft **ASEAN Framework Agreement**, Article 2(f). The Agreement has yet to be approved by the member countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam). Principles are similar to objectives in that they provide the general framework within which action has to be taken. Members are expected to adhere to these principles when implementing national ABS laws and policies.

[65] See later under Chapter III paragraph (2)(b) under Exemptions for Farmers and Breeders, in particular the provisions in the laws of Kenya and Uganda. Some countries in Africa (**Ethiopia, South Africa, Gambia**) have exempted from their ABS laws the crops listed in Annex I of the ITPGRFA.

2. The scope of ABS laws

The scope of the ABS laws and arrangements is considered here. The scope may be divided into (a) the resources covered; and (b) the activities in relation to the resource.

3. The range of resources covered

The coverage of ABS laws is relevant to the food and agricultural sector as it determines to what extent the sector will be affected by these laws. The range of resources covered by the laws and guidelines differ widely. Some countries seem to extend coverage to all biological resources as widely construed.[66] Most other countries limit the scope to genetic resources narrowly and strictly construed.[67] Yet others extend the scope of the laws and guidelines to cover derivatives of genetic resources,[68] including biochemical resources.[69]

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[66] Biological resources are defined to include genetic resources. **Guyana** (under the draft Regulations), **Philippines** (in the context of bioprospecting only), **Bangladesh, India, Ethiopia** (biological resources are covered within the definition of genetic resources), the Australian state of **Northern Territory, Australia**.

[67] **Guyana** (under the draft Regulations), **Kenya, Philippines** (in the context of bioprospecting only), **Afghanistan**, **Bangladesh, Bhutan, Ethiopia, Malawi. Nigeria** appears to use the terms 'genetic resources' and 'genetic material' interchangeably; see section 36 of the Nigerian National Park Decree 1999, which regulates genetic and biological material found in national parks only, **Gambia, Hawaii** (genetic or biochemical resources from plants, animals, or microorganisms), , **Costa Rica** (wild or domesticated, terrestrial, marine, freshwater or aerial), **Andean Decision 391** (includes genetic resources of the migratory species that for natural reasons are found in the territories of the Member Countries. Genetic resources are defined as all biological material that contains genetic information of value or of real or potential use), **Bolivia.**

[68] **Guyana** (under the draft Regulations, and only in a specific context, namely: in the event that a commercial product is derived from specimen obtained in Guyana and a patent application is made with respect to such products, the parties to the Research Agreement shall inform the Government of Guyana within thirty days of the filing of the patent application. 'Derived products' include molecules, combinations or mixtures of natural molecules including raw extracts of living or dead organisms), **Kenya** ('derived products'), **Philippines** ('by-products and derivatives', namely 'any part taken or substance extracted from wildlife, in raw or in processed form' including stuffed animals and herbarium specimens), **South Africa** (included in the definition of 'indigenous biological resource'; in relation to an animal, plant or other organism, 'derivative' means 'any part, tissue or extract, of an animal, plant or other organism, whether fresh, preserved or processed, and includes any chemical compound derived from such part, tissue or extract'), **Bangladesh** ('derivatives'), **Ethiopia** (derivatives are included within the definition of 'genetic resource'; 'derivative' means 'product extracted or developed from biological resource this may include products such as plant varieties, oils, resigns, gums, chemicals and proteins'), **Queensland** ('native biological material' includes a substance sourced from a native biological resource; 'sourced from native biological material' means produced by, or extracted or otherwise derived from the material, or synthesised from the material'), **Hawaii** ('samples or derivatives'), **Pakistan**, **Uganda** ('derivatives' means an unimproved or unmodified biologically active chemical compound associated with targeted biological or genetic material formed by the metabolic processes of the organism, modified and used in a technological application, and includes molecules, combinations or mixtures of natural molecules including raw extracts of living or dead organisms and soil matter, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) or chemical compounds, modified, created or synthesised from genetic material originally obtained in accordance with these Regulations), **Vanuatu, India** ('by products and derivatives'. Derivatives are covered indirectly under the definition of research which means study or systematic investigation of any biological resource or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use), **Andean Decision 391** ('by products' defined as a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings), **ASEAN Framework Agreement** (also extends to products by the definition of derivatives: extracts from biological and genetic resources such as blood, oils, resins, genes and seeds, spores, pollen and the like, as well as the products derived from, patterned on, or incorporating manipulated compounds and/or genes), **Bolivia** ('by products').

[69] **Hawaii, Bhutan, Costa Rica. Hawaii** does not define biochemical resources. **Bhutan** define biochemical resources as 'any material derived from plants, fungi, animals or micro-organism, which contains specific characteristics and special molecules' while **Costa Rica** has adopted an identical definition with the addition of 'elements to design them'. The Costa Rica laws explain that in contrast to the organic use of resources, the biochemical resource undergoes a greater technical-industrial transformation and exploitation, and generally contains a greater number of active ingredients – Article 7.3, Article 6(f).

Some of the countries that only include genetic resources within the scope, have not defined the term.[70] Some have adopted the definition (or a similar definition) in the CBD;[71] yet others adopt as well the definition of 'genetic material' given in the CBD.[72]

Of the countries that extend coverage to biological resources, some have not provided a definition for the term,[73] while some others have adopted the definition given in the CBD.[74] Several countries have adopted a variation that involves the use of some parts of the CBD definition of 'biological resources'.[75]

Some mention 'biological resources' of native species but regulate only the research and development on the genetic resources (or biochemical compounds) comprising or contained in the biological resources.[76] Some countries provide expressly that both *in situ* and *ex situ* resources are covered.[77]

Some countries have utilized different concepts to describe the resources covered by their ABS laws, such as 'indigenous biological resource',[78] 'native biological material',[79] and 'components of genetic

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[70] **Guyana, Kenya**, **Bolivia** (not defined but its law explicitly implements the **Andean Decision 391** where the term is defined), **Hawaii**.

[71] **Nigeria, Philippines, Bangladesh, Malawi, Uganda, Vanuatu, Gambia, ASEAN Framework Agreement**. The CBD definition: 'means genetic material of actual or potential value'.

[72] **Afghanistan, Bhutan, Ethiopia, Northern Territory, Australia**. The CBD definition of genetic material: 'any material of plant, animal, microbial or other origin containing functional units of heredity'.

[73] **Guyana, Pakistan**.

[74] The CBD definition: 'includes genetic resources, organisms, or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity'. **Philippines, Ethiopia, Northern Territory, Australia, ASEAN Framework Agreement.**

[75] **Bangladesh** ('biological resources include all biological resources, organisms or parts thereof, populations, or any other biotic components of ecosystems of Bangladesh'), **Nigeria** ('biological material' is defined as including 'genetic material, organisms or part thereof, population or any other biotic component of the ecosystem'), **India** ('biological resources' means plants, animals and micro organisms or parts thereof, their genetic material and by products (excluding value added products) with actual or potential use or value), **Sabah** ("Biological resources" include genetic resources or materials of plant, animal or microbial origin or any other biotic components of the ecosystem, with actual or potential use or value for humanity).

[76] **Australia** Regulation 8A.03(1), Environment Protection and Biodiversity Conservation Regulations 2000. **Northern Territory** has a similar provision: s. 5(1), Biological Resources Act 2006.

[77] **Philippines** (*ex situ* collections of biological resources sourced from the Philippines, except for collections currently accessed under international agreements where the Philippines is a party), **Bangladesh** (resources within the jurisdiction of the country, both *in situ* and *ex situ*), **Bhutan** (resources both *in situ* and *ex situ* found within the territory of the Kingdom of Bhutan), **Ethiopia** (resources found both *in situ* and *ex situ*), **Hawaii, Pakistan** (existing in the national jurisdiction of the country), **Uganda, Brazil, Costa Rica, Bolivia** implementing **Andean Decision 391** (where member states are country of origin), **ASEAN** (The scope even extended to include biological and genetic resources in *ex situ* collections outside the region in accordance with national legislation and international commitments), **Sabah** (The scope cover *ex situ* collections maintained by the State. *Ex situ* includes biological resources that are housed, planted, stored, kept or found outside their natural habitats such as in herbariums, research institutions, universities, botanical gardens, private collections and any other similar conservation centres).

[78] **South Africa.** Term includes:

any resource whether gathered from the wild or accessed from any other source, consisting of any living or dead animal, plant or other organism of an indigenous species (that occurs naturally and excludes that introduced by human activity); its derivative or genetic material;

any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any such animals, plants or other organisms;

any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the use of biotechnology, have been altered with any genetic material or chemical compound found in any indigenous species or any animals, plants or other organisms referred to above;

when used in relation to any matter other than bioprospecting, the term includes any resource referred to in (a).

[79] **Queensland.** It means: (a) a native biological resource; (b) a substance sourced, whether naturally or artificially, from a native biological resource; or (c) soil containing a native biological resource. Native biological resource is defined as: (a) a non-human

heritage'.[80] Some countries with wide scope exclude biological resources but only in specified circumstances.[81]

Generally it can be stated that despite the variation in the coverage, and even the lack of a definition, GRFA appear to be included in the scope of all the countries. For example, often, where 'biological resource' is referred to and the term is not defined, GRFA can be presumed to be covered by the legislation, by implication.

The draft law of **Pakistan** on access to biological resources, for example, states in its preambular paragraph, the need to implement the relevant provisions in the CBD relating to access to genetic resources.[82] **Bolivia** states the scope of its law as regulating access to genetic resources – without defining the term. But its law explicitly implements the **Andean** Decision 391 where the term genetic resource is defined as, all biological material that contains genetic information of value or of real or potential use.[83]

Most countries do not distinguish between domesticated and wild genetic resources. Some countries explicitly include both in the scope of their ABS laws.[84] Most others include it impliedly as the scope does not exclude domesticated resources from their scope. This plainly has quite immense implications for GRFA as, if the scope of the laws is limited to wild or natural biological or genetic resources, there would be no overriding access requirements to fulfil. Some laws limit the access provisions to the flora and fauna that is being protected and conserved in a national park. This implies that domesticated resources are excluded from the scope of this specific sectoral law.[85]

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living organism or virus indigenous to Australia and sourced from State land or Queensland waters; or (b) a living or non-living sample of the organism or virus.

[80] **Brazil.** This is defined as information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form of molecules and substances originating in the metabolism of these living beings, and in extracts obtained from *in situ* conditions, including domesticated, or kept in *ex situ* collections, if collected from *in situ* conditions, within the Brazilian territory, on the continental shelf or in the exclusive economic zone.

[81] **Hawaii.** The exclusion is limited to the taking of the biological resource from an area traditionally used in accordance with traditional customary practices; biological samples that are part of usual practices in crop cultivation; or biological resources for any commercial or related non commercial activity such as fishing for commerce or recreation, collecting broodstock for, and harvesting of trees, plants and flowers.

[82] Article 3 of Pakistan Draft Law on Access 2004: 'The legislation applies to biological resources and [related] knowledge and technologies as well as their derivatives existing in the national jurisdiction of the country'.

[83] The Decision covers all genetic resources of which member States are countries of origin and held in *ex situ* and *in situ* conditions, their by-products, intangible components and the genetic resources of the migratory species that for natural reasons are found in the territories of the Member Countries - Article 3.

[84] **Philippines:** Joint Implementing Rules and Regulations pursuant to Republic Act No. 9147 [Joint DENR-DA-PCSD Administrative Order # 01, Series of 2005, section 2.1 – *The Guidelines apply to bioprospecting activity of any biological resources including wildlife, domesticated or propagated species...;* **Bhutan,** The Biodiversity Act, 2003 section 3.a: applies to all the genetic and biochemical resources including wild, domesticated and cultivated species of flora and fauna …; **Bangladesh**, Bangladesh Biodiversity Act 1998, Article 3(3), includes all biological and genetic resources …implies all varieties of life forms including … wild or cultivated …. **Bulgaria,** Biological Diversity Act 2002, Article 66(1) and (2), access is to the natural flora and fauna See also **Costa Rica** and **South Africa,** South African Act 2004, section 1 read together with section 80(2)**, Brazil**, Brazilian Provisional Act, section 7(I).

[85] **Nigeria**, National Park Service Decree 1999, section 36(1) read with the definition of national park in section 53.

4. The range of activities covered

The scope of the laws and guidelines are also limited by the activities they cover. These range from the inclusion of all activities in relation to the genetic resource[86] to only those activities that are specifically referred to by the laws or guidelines. The activity is invariably described by reference to its purpose. This implies that any other activity that is thus impliedly excluded or unrelated to the particular stated purpose would be outside the regulatory process of the ABS law or arrangement. This part does not list and discuss the activities that some countries explicitly exclude from their laws. These are discussed later (see subheading 'Exemptions').

The authorized activities relate mainly to access for the purpose of research and/or commercialization. The following observations may be made:

- Most countries refer to research activity directly.[87] Some include research activity within the definition of 'bioprospecting.[88]
- Some countries do not state the purpose of the research.[89]
- Most state (either in addition or by itself) the objective of research (either referred to directly or as part of bioprospecting) – as having a commercial purpose, described variously as: commercial use, commercial purpose,[90] 'with a view to commercialization',[91] commercial product

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[86] Example **Sabah**: access means all activities relating to the prospecting, collection, commercial utilization and research and development of biological resources or associated relevant knowledge. There is no definition for prospecting, collection, commercial utilization or research: Article 2, Sabah Enactment.

[87] **Uganda**, **Pakistan, Vanuatu** (The law regulates bioprospecting. 'Research' is one of the purposes for which bioprospecting may be carried out. 'Research' includes investigative research and sampling)**, Costa Rica, India** (Research means any study or systematic investigation of any biological resource or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use) **Andean Decision 391**, **ASEAN Framework Agreement, Sabah, Guyana** (Under the Guidelines, research is described as including 'gathering biological and genetic material as well as ethnobiological knowledge)**, Kenya, Philippines** (The collection and utilization of biological resources for scientific research and not for commercial purposes. Scientific research refers to the systematic collection, study and discovery of potential use/s of biological resources to generate basic scientific knowledge as governed by Section 15 of the Wildlife Act and its implementing rules), **South Africa** (Any other kind of research' means research other than bioprospecting and includes the systematic collection, study or investigation of indigenous biological resources, conducted under the auspices of a *bona fide* research institute or organization to generate scientific knowledge, but excludes incidental surveys and searches), **Bhutan, Australia** (Taxonomic research and/or other research).

[88] **Costa Rica** (Bioprospecting means the systematic search, classification and research for commercial purposes of new sources of chemical compounds, genes, proteins, and micro-organisms, with real or potential economic value, which are found in biodiversity), **India** (The law regulates bio-survey and bio-utilization. This means the survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and includes characterization, inventorisation and bioassay), **South Africa (**Bioprospecting, in relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation)**, Bhutan** (Bioprospecting means the systematic search, classification and research of new sources of chemical compounds, genes, proteins and microorganism for commercial purposes with real or potential economic value, which are found in biodiversity), **Guyana** (Bioprospecting is defined as the research, collection and utilisation of biological and genetic resources for purposes of applying the knowledge derived therefrom to scientific or commercial purposes and includes research related to timber and mining activities'), **Philippines** (Bioprospecting means the research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived therefrom solely for commercial purposes), **Northern Territory** (The law regulates bioprospecting. Bioprospecting means the taking of resources for research in relation to any genetic resources, or biochemical compounds, comprising or contained in the resources).

[89] **Uganda, Pakistan, Andean Decision 391, ASEAN Framework Agreement 2004, Sabah, Kenya, Bhutan**.

[90] **Philippines** (bioprospecting means the research, collection and utilization of biological and genetic resource for purposes of applying the knowledge derived therefrom solely for commercial purposes).

[91] **Costa Rica** (bioprospecting means the systematic search, classification and research for commercial purposes of new sources of chemical compounds, genes, proteins, and micro-organisms, with real or potential economic value, which are found in

development,[92] commercial gain,[93] commercial utilization,[94] industrial application or biodiscovery.[95]

- Some countries provide for commercial use[96] and industrial application,[97] in addition to, and not as a purpose of the research.
- Many countries refer to the term 'bioprospecting' as noted earlier. However there seems to be no common definition. Some do not even define the term.[98] Those who do, invariably include a commercial purpose within the term.[99]
- One country defines bioprospecting to include a scientific (non-commercial) purpose;[100] some others extend it to conservation as well.[101]
- Some variations include, as a distinct purpose and in addition to research and commercial utilization, bio-survey and bio-utilization. This seems to cover taxonomy related purposes.[102]
- Some countries include conservation as a distinct purpose.[103]

The inclusion in the scope of the ABS laws of a list of activities and their purpose seems to imply that, in these countries, no approval is required for activities for purposes that are not listed. The activities thus impliedly excluded would be: collection for personal use or consumption, trading of resources that are commodities, and, accessing resources for the purposes of conservation. Some countries include access for the purpose of taxonomy within their ABS law. This suggests that perhaps where this is not specifically mentioned, access approval for such purposes is excluded from the law. Taxonomy especially in respect of genetic resources for crops may have a use value as taxonomy identification keys assist in pinpointing the damaging presence of invasive alien pests. This facilitates the introduction of biological control agents to eradicate the pests.[104] This has implications for biodiversity, conservation and food security.[105]

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biodiversity), **South Africa** (bioprospecting, in relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation), **Bhutan** (bioprospecting means the systematic search, classification and research of new sources of chemical compounds, genes, proteins and microorganism for commercial purposes with real or potential economic value, which are found in biodiversity).

[92] **Australia**.

[93] **ASEAN Framework Agreement** (bioprospecting means the collection of biological and genetic material for commercial gain).

[94] **India** (the law regulates any end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention), **Sabah.**

[95] **Northern Territory** (biodiscovery means research on samples of biological resources, or extracts from those samples, to discover and exploit genetic or biochemical resources of actual or potential value for humanity), **Queensland** (biodiscovery includes biodiversity research, which means the analysis of molecular, biochemical or genetic information about the resource for the purpose of commercializing the material).

[96] **Uganda, Pakistan, Vanuatu, Costa Rica, Andean Decision 391, ASEAN Framework Agreement, Kenya, Bhutan**.

[97] **Uganda, Vanuatu, Andean Decision 391, ASEAN Framework Agreement, Kenya**.

[98] **Andean Decision 391, Kenya**.

[99] **Costa Rica, India, South Africa, Bhutan, Guyana, ASEAN Framework Agreement, Philippines, Northern Territory**.

[100] **Guyana.**

[101] **Vanuatu.**

[102] **India** (bio-survey and bio-utilization means the survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and includes characterization, inventorisation and bioassay).

[103] **Andean Decision 391, ASEAN Framework Agreement, Kenya, Bhutan, Uganda, Hawaii.**

[104] Taxonomic identification keys helped Thai scientists to detect the presence of a pest *A. dispersus.* A potential biocontrol agent, *Nephasis oculatus*, was then introduced from Hawaii to help lessen the infestation and provide an eventual long-term

5. Implications for food and agriculture

No law or guidelines examined refers specifically to GRFA, except in the laws of a very few countries, exempting PGRFA that are covered by the ITPGRFA (see following section).Very few instruments seem to distinguish between genetic resources for food and agriculture and other uses of genetic resources. However, the varied definitions of genetic resources/genetic material parallel those in the CBD and are thus broad enough to encompass such resources.106 The coverage bears a direct relationship to the food and agricultural sector as it determines to what extent the sector will be affected by the ABS laws and policies. Broad and extensive coverage over a wide range of genetic resources, that would thus include GRFA, and activities could tend to stifle free use and exchange, if each time access is sought, a permit has to be first obtained and the other requirements fulfilled. This, as discussed earlier, is inimical to the continuous research and development so necessary for the food and agriculture sector and achieving food security. Conversely, the exclusion of certain resources and activities from the scope increases the potential for such free use and exchange and enhanced food security.

6. Exemptions and their implications for food and agriculture

Generally, countries are concerned that their genetic resources could be taken and exploited without their consent or they would not be able to secure any, or equitable, benefits from the commercial utilisation of the resources accessed. For these reasons, ABS laws impose requirements that applicants must fulfil for the grant of access. Where these requirements are strict, and the access procedures cumbersome, specific exemptions may, like the implied exemptions discussed earlier, also similarly ameliorate these strict requirements by explicitly exempting certain resources and activities from their scope. They may also exempt persons by allowing access without the need to apply. This section examines the various exemptions and their ambit as well as the implications for food and agriculture and food security. Generally exemptions from the scope of laws facilitate the continued flow of GRFA to farmers and breeders and allow research and improvement of these resources to continue unhindered. Additionally, insofar as most countries make their ABS laws applicable to all – that is persons within the country seeking access to genetic resources - then exemptions will have the same beneficial effect. For this reason, these exemptions for nationals seeking access to genetic resources within the country, are also included.

6.1. Plant genetic resources for food and agriculture

Some laws exclude PGRFA listed in Annex 1 of the ITPGRFA form their scope. The rationale for this exemption is, as discussed earlier, Contracting Parties to the Treaty have agreed to take the necessary legal or other appropriate measures to provide facilitated access and ensure benefit-sharing for these crops through the Multilateral System of ABS established under the ITPGRFA. Such access will be to other contracting parties and to legal and natural persons under their jurisdiction. Not all of the crops listed in Annex 1 are automatically included in the Multilateral System. Only those that are under the management

control. The cost was less than a few thousand US dollars. Today the pest only occurs sporadically. This pest attacks any broad-leaved crops and fruit trees such as guava and mango: *Why Taxonomy Matters,* BIONET, series no. 1 (www.bionet-intl.org/why) citing Waterhouse and Sands, *Classical Biological Control of Anthropods in Australia*, CSIRO Entomology, Australian Centre for Agricultural Research, Canberra, 2001,at p. 559.

[105] Select Committee on Science and Technology, 2002, Third Report of the UK House of Lords; http://www.publications.parliament.uk/pa/ld200102/ldselect/ldsctech/118/11801.htm. See also the critique for regulating the free exchange of specimens for taxonomic research: KD Prathapan et al, 'Death Sentence on Taxonomy in India', *Current Science,* vol. 94, No. 2, 25 Jan 2008, at p. 170.

[106] See for example: Regulation 2 of Kenyan ABS Regulations 2006.

and control of the Contracting Parties and are in the public domain are included.[107] Further Contracting Parties have agreed to grant access through a standard Material Transfer Agreement (SMTA).[108] This avoids the need for bilateral dealings for each access transaction. The agreed terms of the benefit-sharing are also set out.[109] One important condition is that access will be provided solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture. There can also be no claim of IPRs or other rights that limit facilitated access to the materials or their genetic parts or components, in the form received from the Multilateral System. Also, access is subject to the PIC of the Party providing the resources.

A striking innovation in the SMTA is a requirement that recipients who commercialize products that are PGRFA and incorporate materials accessed from the Multilateral System pay into an international fund or other mechanism established by the Treaty, an equitable share of the benefits arising from the commercialization of the product. The payment is mandatory if restrictions are placed on the availability of the product for further research and breeding, such as by a claim for patents. Where there are no such restrictions, Parties are encouraged to make the payment. The benefits arising from the use of PGRFA are to flow directly or indirectly to farmers in all countries who conserve and utilize PGRFA, especially those in developing countries and countries with economies in transition.

In addition, there are a range of other benefits to be shared, such as information, capacity building and access to and transfer of technology. These are to help developing countries to enable them to conserve and utilize their own PGRFA as well as those they may access from the Multilateral System. While this System covers only the listed crops, the Treaty nonetheless sets a framework for the conservation and sustainable use of all PGRFA and establishes the institutional machinery to oversee the implementation of its provisions.[110]

As noted earlier, some Parties to the ITPGRFA with ABS laws, exclude crops covered by Annex 1 of the Treaty from the scope of their laws.[111] These, as stated earlier, are the crops that are under their management and control and are in the public domain. **Ethiopia** has a special section in its general law that incorporates the Multilateral System's facilitated access scheme into its law.[112] Other Parties to the ITPGRFA do not reflect their obligation to provide facilitated access to such crops in their ABS law. In some other countries, an exclusion of such crops is currently under consideration, even though they are not Contracting Parties to the ITPGRFA. **South Africa,** which is not yet a party, excludes these resources from its draft law,[113] likely in view of its anticipated ratification of the ITPGRFA.[114] Interestingly, **Gambia**, although not a Party to the ITPGRFA, has recognized the need for ABS and emphasized the

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[107] Also included are the crops in Annex 1 and held by the IARCs of the CGIAR or by other entities that have voluntarily included them in the Multilateral System. Parties to the Treaty are obliged to take appropriate measures to encourage natural and legal persons in their countries to include their holdings of crops listed in Annex I to the Treaty in the Multilateral System.

[108] Article 12.4, ITPGRFA.

[109] Article 13, ITPGRFA.

[110] *Explanatory Guide to the International Treaty of Plant Genetic Resources for Food and Agriculture,* IUCN, 2005, at pp. 1-2.

[111] **Bhutan,** Section 4(d), Bhutan Biodiversity Act 2003. Exempts from the Act the plant and animal genetic resources covered by the Multilateral System for ABS, 'especially in the case of plant genetic resources for food and agriculture in accordance with international law'. Although the law **of Uganda** does not explicitly exempt the PGRFA in the ITPGRFA from the scope of its law, it has declared this to be so in its Third National Biodiversity Report to the CBD of January 2006 (at p. 119). It has further reported that a new law specific to PGRFA is being drafted to take care of, among other things, the Multilateral System of ABS.

[112] Article 15(2), Ethiopian Proclamation 2006. This is to be implemented through regulations.

[113] Section 80(2)(b)(iii) of South African Act 2004.

[114] In its third National Biodiversity Report to the Convention on Biological diversity, South Africa stated that one of the five-year targets under its National Biodiversity Strategy and Action Plan is to ensure that all transfers of genetic resources are in line with the Convention on Biological Diversity and the ITPGRFA. Nov 2006, pg 60.

importance of complementarity between the national ABS system and the International Treaty.[115] Its National Environment Management Act 1994, has a solitary provision that provides for ABS law in general terms. Although the power in the Act to make regulations and guidelines on access to genetic resources[116] has yet to be exercised, in the light of its intent stated to the CBD, it may be assumed that it intends ultimately to provide for PGRFA in some form or other.

The Bonn Guidelines – which have undoubtedly inspired the ABS laws of several countries – propose that the Guidelines be applied 'in a manner that is coherent and mutually supportive of the work of relevant international agreements and institutions' and specifically mentions that the Guidelines should be without prejudice to the ABS provisions of the FAO ITPGRFA.[117]

6.2. Exemptions for farmers/breeders

The provisions in the laws and other measures of the countries studied ranged from no exemptions at all to farmers and breeders for access to genetic resources,[118] to those that provide some form of exemption;[119] and those that provide complete exemption. Some recognise Farmers' Rights[120] and require permits to access genetic resources managed or innovated by farmers and farmers' innovations are protected, there is no provision exempting farmers from the access requirements if they themselves wish to access genetic resources for breeding.[121]

Some exempt the traditional rights of farmers under the general rubric of preventing any commercial exploitation that is necessary to protect public order or morality.[122] This seems to entitle farmers and breeders to access materials for use in farming and breeding. Some exemptions from the scope are implied by the exclusion of activities from 'commercial utilization'[123] or other concepts peculiar to the law of the country.[124]

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[115] Third National Biodiversity report, 2006 at p. 105. This is stated in its Biodiversity and Wildlife Policy (2003).

[116] Section 35(2) Gambian Environment Act.

[117] Article 10

[118] **Malawi, Costa Rica,** and **Sabah.**

[119] **India, Philippines, Hawaii, Uganda and Kenya** and **Bhutan.**

[120] FAO Conference Resolution 5/89. The ITPGRFA places the responsibility of realizing Farmers' Rights on national governments and lists some of the measures for protecting and promoting these rights: Article 9.2.

[121] **Costa Rica.**

[122] **Bhutan.** Exemption: section 4(f); Objective: section 2(h), Bhutan Biodiversity Act 2003. For content of Farmers' Rights see also: ITPGRFA, Article 9.1 – 9.3. a crucial aspect is the right of farmers to have, use, exchange and sell farm-saved seed and propagating material. The farmers and breeders' right entitlement to access materials is based on this provision, combined with the objective of its law recognizing and protecting farmers' and breeder's rights.

[123] India requires foreign persons and entities and non-resident Indians to obtain approval for access for commercial utilization. Such utilization excludes: conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping Section 2(f) Indian Biodiversity Act 2002. This provision seems to imply that foreign and non-resident Indian nationals are exempt from the ABS requirements for activities excluded from the definition of 'commercial utilisation', including activities of conventional breeding or traditional practices in use in the specified agricultural field.

124 Among the 'non- bioprospecting' activities that Hawaii exempts (by its Draft Bill on Bioprospecting 2007, section 1) from its access provisions are the taking of biological samples that are part of usual practices in crop cultivation, animal husbandry, and aquaculture; and biological resources for any commercial or related non commercial activity such as collecting broodstock for (and harvesting of) trees, plants, and flowers. Although the term 'part of usual practices' is not defined,(Bioprospecting is defined as any activity undertaken to harvest or exploit, for any purpose, samples or derivatives, in situ or ex situ, of genetic or biochemical resources from plants, animals, or microorganisms, section 1), this provision seems to exempt farmers and breeders from the access requirements of the law.

In any event, any exemption from the ABS approval process does not excuse compliance with other laws. A relevant law would be that relating to plant variety protection (PVP) which grants proprietary rights to breeders for new varieties. However, these laws invariably include a breeder's exemption. Under this exemption, the breeder's authorization is not required for the utilization of the protected variety as an initial source of variation for the purpose of creating other varieties and for the marketing of such other varieties;[125]or acts done for the purpose of breeding new varieties and for exploiting these other varieties, provided that the new variety is not essentially derived from the initial variety.[126] The breeder's exemption thus provides space for farmers (and researchers, where there is a researchers' exemption) to carry on with their activities unhindered by the exercise of the breeder's rights, and arguably allows as well space for farmers to develop new varieties and market them.[127] One of the main justifications for PVP is that breeders should be able to secure returns on their investments, but without preventing other breeders (and this includes farmers in the informal breeding sector) from being able to freely access breeding material in order to develop their own varieties.[128]

A few countries[129] exclude from the purview of their ABS laws, genetic resources derived from plant breeders in accordance with the relevant plant varieties law. Although this seems to suggest that this material can be accessed freely and, inferentially, may be used for breeding,[130] what it implies is that for access to such materials, there must be compliance with these other relevant plant variety laws. But as noted, there is invariably a breeder's exemption in such IP laws that allow access to the use of the protected variety without the proprietor's authorization as an initial source of variation to create new varieties and even market them.[131] The exclusion from the ambit of the ABS law and/or subjecting access to these resources to the PVP laws reflects the policy of countries to allow exchange among farmers of seeds and to allow breeders to use the protected varieties. This policy will be negated if access to the use of such resources is restricted by the country's ABS laws. This will be the case if there is no such exclusion. This could have potentially severe adverse implications for the free use and exchange of GRFA and for food security.

Kenya in addition has an interesting provision that attaches an implied condition to an access permit – that reasonable access to all (plant) genetic resources collected, wherever held, shall be guaranteed to all its citizens.[132] This suggests that farmers would have reasonable access to these genetic resources including for breeding purposes. However, this must be read together with a provision in its law, referred

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[125] UPOV 1978, Article 5(3). The exemption represents a major departure from patent law which normally has a very narrow research exemption, often limited to non-commercial scientific or experimental use: Geoff Tansey and Tasmin Rajotte (eds), *The Future of Control of Food,* Earthscan, London, 2008, pp 37 and 42.

[126] UPOV 1991, Article 15.

[127] Biswajit Dhar, *Sui Generis Systems for Plant Variety Protection: Option under TRIPS – A Discussion Paper,* Quaker UN Office, Switzerland, 2002, p.11.

[128] Geoff Tansey and Tasmin Rajotte (eds), *The Future of Control of Food,* Earthscan, London, 2008, p. 38.

[129] **Uganda:** Regulation 4(2)(c), Uganda ABS Regulations 2005, **Kenya:** Regulation 3(b), Kenyan ABS Regulations 2006 and the **Northern Territory of Australia.**

[130] **Uganda**: 'Plant breeders' is as defined by the law relating to plant breeding and plant variety. For Kenya the genetic resources must be derived from plant breeders in accordance with the Seeds and Plant Varieties Act 1972.

[131] Uganda does not have a PVP law. As the exemption is said to apply to genetic resources derived from plant breeders as defined by such a law and there is no such law, it would appear that this exemption will not apply. For Kenya, the Seeds and Plant varieties Act 1972 applies. It does not explicitly allow the farmer/breeder to market any new variety created from the use of the protected variety.

[132] Regulation 15(2)(c), Kenyan ABS Regulations 2006.

to above, that the genetic resource must be derived from plant breeders in accordance with its Seed and Plant Varieties Act.

6.3. Exemptions for research activities

The countries surveyed had provisions that ranged from a research exemption for non-commercial (or non-profit) purposes[133] to no exemptions at all.[134] Some relaxed the requirements for research in some situations and for certain applicants.[135] This is dealt with later.[136]

Some exempt approved research activities involving genetic resources with a rider – the research must be intended for educational purposes by recognised institutions . This is limited to research that must not result in commercial purposes or export to other countries.[137] A few limit the research exemption to its citizens, including or to collaborative ventures with its citizens by foreigners.[138] [139] The Malaysian state of **Sabah** is empowered to exempt individual, academic and research institutions seeking to undertake any pure academic and non-profit oriented research from the access application. **Kenya** requires research authorization from the relevant authority for all applicants. Both national as well as foreigner researchers must have an affiliating institute in Kenya. However, it exempts approved research activities intended for educational purposes within recognized Kenyan academic and research institutions.[140] In the **Philippines**, activities for the purpose of non-commercial scientific research are not exempted from access procedures but are subject to a separate and more relaxed procedure (discussed later).[141] However, there is a complete exemption from these rules in respect of the collection of specimens or samples by government agencies necessary to address urgent concerns such as, but not limited to, red tide, Ebola or Ebola-like virus and malaria occurrences - ostensibly for scientific research.[142]

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[133] **Uganda, Sabah, Kenya, Philippines.**

[134] **Vanuatu, Costa Rica, India, Guyana, Nigeria, Queensland, Northern Territory** and **South Africa**.

[135] **South Africa**, **India.**

[136] See later: Chapter IV paragraph (3)(a).

[137] Regulation 4(2), **Uganda** ABS Regulations 2005.

[138] **India:** researchers neither require prior approval nor need to give prior intimation to the relevant authority for obtaining biological resource for conducting research in India. The website of the National Biodiversity Authority of India: www.nbaindia.org/faq.htm. Foreign institutions that collaborate with Indian institutions also do not need access approval for research projects involving the transfer and exchange of biological resources, or information relating to the resources: Section 5 of the Indian Biodiversity Act 2002. These 'collaborative research projects' must be approved by the government and conform to its guidelines. The projects are those sponsored under the bilateral and multi-lateral agreement, MOU and work plan under the International Collaborative Research Projects: Guideline 1(3) of Indian Guidelines for Collaboration Research Projects 2006. There is nonetheless criticism that the research is unduly hampered by overly restrictive access requirements. See K S Jayaraman, *Nature* 452, 7 (2008). A collaborative project to study the insects was reportedly derailed by the Indian NBA for biopiracy concerns.

[139] The projects are those sponsored under the bilateral and multi-lateral agreement, MOU and work plan under the International Collaborative Research Projects: Guideline 1(3) of Indian Guidelines for Collaboration Research Projects 2006. There is nonetheless criticism that the research is unduly hampered by overly restrictive access requirements. See K S Jayaraman, *Nature* 452, 7 (2008). A collaborative project to study the insects was reportedly derailed by the Indian NBA for biopiracy concerns.

[140] Regulation 3(d) of Kenyan ABS Regulations 2006. There is an added phrase at the end of this particular exemption '*…which are governed by relevant IP laws'*. The meaning of this is not clear. It seems to suggest that the exemption from the law does not exempt the person from abiding by any IP laws. This means that if the researcher wishes to access genetic resources, and these are subject to IP rights, then the researcher must respect these rights.

[141] Such activities are governed by the Implementing Rules and Regulations while bioprospecting activities (bioprospecting being defined as activities conducted solely for commercial purposes: section 5 of the Philippines Guidelines for Bioprospecting 2005) are governed by the Guidelines.

[142] Rule 15.7 of the Philippines IRR 2004.

Implementing any research exemption – for non-commercial purposes – presents some difficulty primarily because the line between commercial and non-commercial research is often blurred.[143] It is not uncommon for the private sector to fund public research with the expectation of commercializing the end result.[144] The model in the USA and the other OECD countries, and replicated the world over, promotes public universities and research institutions to engage in the commercialization process by owning inventions through IPRs and to work with industry to bring products to the market. The OECD promotes this model to turn 'Science into Business'.[145] The financial inducement is great as it can generate substantial income for universities and research institutes.[146] This ultimately facilitates knowledge and resource appropriation through research, publication, or sponsorship arrangements, even when the researchers' intentions are purely academic.[147] In the field of GRFA, research in respect of food and agriculture typically and ultimately aims at commercial use and circulation of agricultural products. Hence, any research exemption provided by ABS laws may be of very limited practical significance for food and agriculture. Further, the exemption should only be in respect of compliance with the strict access procedures, and not from the benefit-sharing requirements, in particular sharing the results of the research and development in a fair and equitable way.

Finally, it is noted that even patent and PVP laws provide for research exemptions. PVP laws, for example, allow access to the initial genetic material for breeding purposes. Patent law has a narrower research exemption, often limited to non-commercial scientific or experimental use.[148] With the exception of a few countries, most developing countries apparently do not explicitly provide for an experimentation

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[143] Maureen Wolfson, 'Scientists as Users and Providers: A South African Perspective', in Anon (2004), *International Expert Workshop on Access to Genetic Resources and Benefit-Sharing: Record of Discussion*, 235, at 236..

[144] The Crucible II Group, *Seeding Solutions, V*ol. 2, IDRC, IPGRI and the Dag Hammarskjold Foundation, p. 16. It has been noted that public sector funding for agricultural research has been stagnant or declining. In developed countries this has been accompanied by a rapid growth in private investment. This appears to be the dynamic element in agricultural research and development. This may result in neglect of research for the world's poor. It may also lead in turn to the adoption of monoculture based practices that threaten diversity of genetic resources especially for food and agriculture: Janet Hope, *Biobazaar,* 2008, Harvard University Press, at pp. 101 – 102.

[145] The US Bayh-Dole Act, 1980 allows universities and other public institutions and their employees to seek patent protection for their inventions and retain the royalties: Nuffield Council on Bioethics, The Ethics of Patenting DNA, 2002, at p. 4, para 1.6. for OECD: see Paul Oldham (2004), *Global Status and Trends in IP Claims: Microorganisms,* ESRC Centre for Economic and Social Aspects of Genomics, pp. 16-17.

[146] Susan Kling Finston, 'Relevance of Genetic Resources to the Pharmaceutical industry', in Anon (2004), *International Expert Workshop on Access to Genetic Resources and Benefit-Sharing: Record of Discussion*, 244 at 248.

[147] Kelly Banister , 'Mechanisms for Compliance with ABS by the Academic research Community (Canada), in Anon (2004), *International Expert Workshop on Access to Genetic Resources and Benefit-Sharing: Record of Discussion*, 229. There is a potential for abuse as exemptions granted for research for non-commercial purposes may be in reality and ultimately for commercial ends. There have been attempts to overcome this. For example, deferring the negotiation of benefit-sharing contracts to a time when a commercial result such as a compound is found or is imminent. But this creates other problems. For then, the user's leverage to obtain fair terms could be weakened as it risks losing its entire investment if no agreement is concluded – aside from the delay in re-negotiating a fresh contract. If no agreement results, its initial access approval could be rendered useless. It is noted that some agreements merge the research and commercialization agreement, such as the Ball-SANBI horticulture agreement. However, phased agreements are prevalent in some sectors, - and particularly amenable for use in the pharmaceutical sector where, unlike the food and agriculture sector, there are significant differences in the financial implications and activities undertaken at various phases of the development of the drug: discovery, development and commercialisation.

[148] This is legitimate under Article 30(iii) of the TRIPS Agreement. Geoff Tansey and Tasmin Rajotte (eds), The Future of Control of Food, Earthscan, London, 2008, pp 37 and 42. In some jurisdictions, such as the US, a plant patent holder cannot prevent another from reproducing the patented variety sexually (US Plant Patent Act, 1930, 35 USC s. 161). Also, a plant patent will not necessarily prevent all copying. A competitor is free to independently develop a variety with all the characteristics of the patented plant, if otherwise distinct.' Virginia Bennett, 'Plant Biotechnology', in Kenneth Sibley(ed), The Law and Strategy of Biotechnology Patents, (1994), Butterworth – Heinemann, p. 171 at 173.

exception, including for commercial purposes.[149] It will be ironical if ABS laws restrict access to genetic resources more severely than even IP laws. This may well be the case if ABS laws do not provide for any research exemption or do not simplify access procedures. This would limit rather drastically the free use and exchange of GRFA for research purposes with adverse consequences for food security.

6.4. Exemptions for conservation activities

No ABS law seemed to expressly exempt activity related to conservation from access requirements. Only **Kenya,** in its Forest Act, explicitly exempts from access approval, any conservation activity within a forest included in a management plan.[150] Such activity includes entering a forest and making collections, harvesting, removing or extracting forest produce. This implies that an application by any research institution, including a foreign institution, to conduct basic research aimed at improving sustainable use and management capabilities, may not need to obtain access approval.[151]

However, access to GRFA for conservation purposes may be impliedly excluded from the scope, as discussed earlier. This means that those activities in relation to the purpose – such as accessing biological/genetic resources for conservation purposes would be exempt from access approval requirements. However, the laws do not suggest what happens later to the material accessed for such purposes. In particular, there is no indication that the material exempted is, or maybe used for agricultural research and development. If there is no such use, then this exemption would have little practical significance for GRFA. Nonetheless conservation may be an important first step for current and future development of GRFA as it maintains the pool or diverse 'capital' of resources available for research and development, and on which continuing crop and livestock improvement and productivity depends. Not providing an exemption for conservation purposes would create a significant hurdle in respect of this area of crucial importance for GRFA.

1.6. Exemptions for commodities

Some countries exempt commodities explicitly. **Bhutan** exempts commodities that are for direct use or consumption as the NCA may decide based on the processes and end use of the resource. India provides the possibility of declaring as exempt biological resources normally traded as commodities.152 Ethiopia exempts the sale of produce of biological resources for direct consumption that do not involve the use of genetic resources. Other countries, as noted earlier, do so by limiting the scope of application of their ABS laws to activities such as bioprospecting, which do not include access to commodity related acts.

6.5. Exemptions for government purpose

The **Philippines** provides an untypical exemption for the collection of specimens or samples by government agencies necessary to address urgent concerns. An indicative list of these concerns relate to

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[149] Carlos Correa, *Trade Related Aspects of Intellectual Property Rights: a Commentary on the TRIPS Agreement,* OUP, 2007, at p. 304. The US allows research without the authorization of the patent owner narrowly for scientific purposes only. Whether the use is for commercial purposes or not is not determinative: *Madley v Duke* 64 USPQ 2d 1737 (Fed Cir 2002). In European and other countries, experimentation *on* an invention (not *with* an invention) is allowed even for commercial purposes: Carlos Correa, at p. 304.

[150] Forests Act 2005, section 44 (1) read with section 2. 'Management plan' refers to a systematic programme showing all activities to be undertaken in a forest during a period of at least 5 years, and includes conservation, utilization silvicultural operations and infrastructural development.

[151] Evanson Chege Kamau, 'Sovereignty over Genetic Resources: Right to Regulate Access in a Balance. The Case of Kenya', *Revista Internacional de Direito e Cidadania,* n.3 73 at 79, February 2009.

[152] Section 40 of Indian Biodiversity Act 2002.

health threatening situations.[153] It could conceivably also cover situations that relate to food and agriculture such as controlling pests and meeting emergencies where genetic resources are needed to ensure food security. Public officers in the Malaysian state of **Sabah** who obtain access to biological resources as part of their prescribed duties and responsibilities which does not involve any collaboration with the second and third party, are also exempted from the access application requirements.[154]

6.6. Exemptions for indigenous and local communities

Several countries exempt from the access requirements, the use and exchange of genetic resources among local communities which is intrinsic to, and a part of, their traditional and customary practices**.**[155] This means that there is no need for these communities to obtain permits and negotiate terms of access when they are exchanging the genetic resources amongst themselves, and such exchange is a practice or use that arises from their traditional and customary practices. This also implies that access to genetic resources outside the community and which does not involve traditional and customary practices is still subject to the conditions and procedures for ABS under the law. Some countries[156] exclude traditional use and exchange of biological resources as well as [related] knowledge and technologies carried out by and among local communities based upon their customary practices.[157] Although this seems to extend use and exchange beyond intra- communities, this particular activity must nonetheless be justified as being part of customary practices.

Some countries impose an additional requirement. The use and exchange must also be for a 'non commercial purpose'[158] or 'non-profit making practices'.[159] Some include both these requirements.[160]

The **Philippines**[161] and **Guyana**[162] limit the exemption to traditional use only (and not to exchange as well). However, the exemption appears wide enough to cover the savings and exchange of seeds by farmers carrying out their traditional breeding practices – if these practices form part of their customary utilization of biological and genetic resources (in the case of **Guyana**), and includes the utilization by indigenous peoples, in accordance with their customary practices, of any wild forms and varieties of flora and fauna in all development stages including those which are in captivity or are being bred and propagated (in the case of the **Philippines)**.

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[153] Rule 15.7, Joint Implementing Rules and Regulations pursuant to Republic Act No. 9147 [Joint DENR-DA-PCSD Administrative Order # 01. The Rule states that the concerns are not limited to those set out. The relevant agencies must be informed of the results of the research conducted and recommended plan of action.

[154] Section 15(2) of Sabah Biodiversity Enactment 2000.

[155] **Bhutan, Bangladesh, Costa Rica, Brazil, Andean Decision 391, ASEAN Framework Agreement 2004, Bolivia, Afghanistan, India, Kenya** (Exempting the exchange of genetic resources carried out by members of the local Kenyan communities amongst themselves and for their own consumption: Regulation 3(a) of the Kenyan ABS Regulations 2006) **and Ethiopia.** The Ethiopian law goes on to provide that there shall be '*no legal restriction placed on the traditional system of local communities on the use and exchange of genetic resources and community knowledge'* - Article 8 of the Ethiopian Proclamation 2006.

[156] **Pakistan, Bangladesh.**

[157] **Pakistan.** Article 3.2, Pakistan Draft law on Access 2004. Bracket supplied in original text.

[158] **Afghanistan**. Article 61(2) of the Afghanistan Environment Act 2005.

[159] **Costa Rica.**

[160] **Bangladesh.**

[161] Section 5, Guidelines for Bioprospecting Activities in the Philippines, 2005.

[162] Regulation 4(10), Guyana Draft Regulations 2001.

India extends the exemption to include local people and communities of the area, including growers and cultivators of biodiversity and vaids and hakims,[163] who have been practicing indigenous medicine;[164] and the **Andean Decision 391** to native, Afro-American and local communities of the Member Countries; **Bangladesh** exempts from the scope of its law the traditional use and exchange of biological and genetic resources as well as related knowledge, culture and practices carried out by and between communities based upon their customary and traditional practices, particularly local and indigenous communities as well as communities holding Residual Titles.[165] There is also however a provision that allows any member of the community or any citizen[166] to grant free access to its resources and innovations, knowledge and practices for non-commercial or non-profit purposes. The provision seems to clarify 'free' as meaning without payment. This seems to allow a waiver of the monetary benefits. It does not appear to exempt the person seeking access from complying with the access requirements.

Hawaii exempts genetic or biochemical resources obtained through non-"bioprospecting" activities.[167] Such activities include the taking of biological resources from an area of land or water by Hawaiians and other peoples who have traditionally used the area of land or water in accordance with traditional customary practices. The Australian state of **Northern Territory** provides a similar exemption for activities not falling within the meaning of bio-prospecting. The activities that do not constitute bio-prospecting are given more specificity to include taking biological resources from an area of land or water by indigenous people who have traditionally used the area or water in accordance with aboriginal tradition for hunting, food gathering and for ceremonial and religious purposes.[168] The **Australian** federal law[169] exempts the taking of biological resources by indigenous persons for research and development purpose or in the exercise of their native title rights and interests.

It is noted that most countries extend the exemption to 'associated knowledge',[170] 'traditional knowledge',[171] 'related knowledge',[172] or 'associated intangible components', and to by-products of the genetic resources.[173] **Sabah (Malaysia)** provides no exemption for exchange of genetic and/or biological resources between indigenous communities.

6.7. Exemptions for personal use and consumption

Genetic material accessed for personal use, especially for consumption, is also explicitly exempted by some ABS laws from the need to seek access approval. In the **Philippines**, subsistence (i.e. household)

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[163] *Vaids* are traditional healers; *hakims* are indigenous doctors. Essentially these are traditional health care practitioners residing and/or using biological resources within villages: NBA (India), *People's Biodiversity Register: Simplified Methodology,* December 2008, at p. 5.

[164] Section 7, Indian Biodiversity Act 2002.

[165] Article 3(3), Bangladesh Biodiversity Act 1998. This gives ownership right to a community for the biodiversity and genetic resources to those who live interactively within an ecosystem and whose lives and livelihoods are the result of that interaction. This is distinct from individual ownership. Communities holding such title have rights of use as well as the custodial and stewardship titles to the genetic and biological resources: Article 4(2).

[166] Article 9, Bangladesh Biodiversity Act 1998.

[167] **Hawaiian** Draft Bill on Bioprospecting 2007.

[168] Section 5 of the Biological Resources Act 2006

[169] The term 'access to biological resources' means the taking of biological resources of native species for research and development on any genetic resources or biochemical compounds comprising or contained in the biological resources: regulation 8A.03 of the Australian Environment Regulations 2005.

[170] **Costa Rica.**

[171] **Brazil.**

[172] **Bangladesh.**

[173] **Andean Decision 391.**

consumption and conventional commercial consumption for direct use (e.g. for logging and fishing)[174] of genetic resources are exempted from the scope of the law.[175] **Uganda** excludes genetic resources that are purely for food or other consumptive purposes.[176] Others exempt commodities which clearly are, or could be, for direct use or consumption.[177]

Also as noted earlier, because the coverage of the laws is limited to certain activities defined by reference to the purpose, it may be implied that no approval is required for the acquisition of the resource for purposes other than those included within the scope. This would thus impliedly exclude such activities as acquiring the resource for personal use or consumption.

6.8. Other exemptions

There are also a range of other exemptions that do not strictly fit into the earlier categories. These include the following:

- Taking samples of biological resources that have been cultivated or tended for a purpose other than for research to discover and exploit its genetic or biochemical component and where the samples are not to be used for such a purpose. This implies a non-commercial end use.[178]
- Taking samples of biological resources that are available to the public on an unrestricted basis (whether on commercial or non-commercial terms). This would seem to cover as well commodities and resources for private use.[179]
- A range of activities that are for a purpose other than to discover and exploit its genetic or biochemical component such as: fishing for commerce or recreation, game or charter fishing or collecting broodstock for aquaculture; harvesting wild flowers; taking wild animals or plant for food; taking essential oils from wild plants; collecting plant reproductive material for propagation.[180]
- The use of biodiversity elements utilized as organic resources.[181]

7. Conclusions

These exemptions, taken together with the exclusion of certain resources as well as certain activities, from the scope provide considerable relief from the strictures imposed by the ABS laws requiring access approval and bilaterally negotiated access terms. The exemptions in respect of farmers, breeders as well

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[174] But it must not involve biotechnological processes to develop new commercial products: section 5.1, Guidelines for Bioprospecting Activities in the Philippines, 2005.

[175] Section 3.1 of the Guidelines.

[176] Section 4 (2)(a), Uganda ABS Regulations, 2005. These Regulations do not apply to the exchange of genetic resources where the exchange is certified to be purely for food or other consumptive purposes as prescribed by the relevant laws.

[177] **Bhutan, India**. See the discussion earlier under paragraph 2(e)'Exemption for Commodities'.

[178] **Northern Territory**, section 5(2)(c) read with section 4 (1), definition of 'biodiscovery'.

[179] **Northern Territory**, section 5(2)(e).

[180] **Northern Territory**, section 5(3). There is also an exemption relating to the taking of aquatic life which has been caught, taken or harvested pursuant to a permit under the relevant fisheries law. The Commonwealth of Australia has similar provisions relating to the taking of public resources: regulation 8A.03(4), Environment Protection and Biodiversity Conservation Regulations 2000. **Hawaii** also has an indicative list of similar activities: section 1 of the Draft Bill on Bioprospecting 2007.

[181] **Costa Rica.** Organic resource is defined as any material from living beings, wild or domesticated, which may be utilized as such, as a whole or in its macroscopic parts. This seems to cover biological, and not genetic, resources. These resources will continue to be regulated under sectoral and other specialized laws – such as: Forest Law, Wildlife Conservation Law, INCOPESCA Creation Law, Fishing and Marine Hunting Law.

as those relating to exchange among indigenous peoples and local communities (ILCs) are particularly important as they allow for the continued exchange and use of genetic resources unhampered by the regulatory procedural and substantive access requirements. However, the special recognition of ILCs to use and exchange GRFA between themselves does not seem to extend to farmers or breeders who are not ILCs. Nonetheless, some countries may include farmers within the category of local communities and even indigenous peoples.[182] This has potential implications including for food security as this suggests that the free use and exchange amongst the farming community of GRFA would not require access approval. Even then, to the extent that GRFA may need to be accessed from outside the community, and involve non-traditional practice and use, as may be increasingly the case, access would be hampered by ABS laws. The research exemption, however, has less potential for encouraging free use and exchange of GRFA, given the fine line separating research for commercial and for non-commercial purposes and the fact that the exemption is limited to non-commercial purposes. As noted earlier, in the field of GRFA, everything starts off with research and then 'spins out' into the commercial sector. It is noted that where countries fail to provide for exemptions, access to genetic material under the ABS laws may even be more restrictive than under the patent and other PVP laws.

It was noted that the exemptions for conservation purposes may be an important first step for current and future development of GRFA as it maintains a pool of resources available for research and development. Not providing an exemption for conservation purposes would create a significant hurdle in respect of this area of crucial importance for GRFA.

Finally, the exemptions for government purposes may be of importance especially in critical situations when there is a threat to its GRFA or when a country's food security is threatened. There may then be a need to address these concerns by allowing for ready access to genetic resources. Very few countries, however, include such an exemption. This may be because governmental authority may in any case be exercised under other general laws and provisions to address any such exigency.

[182] **Bangladesh**, for example, defines 'community' by reference to any of a number of characteristics. Farmers could fall within this definition: Article 4, Biodiversity and Community Knowledge Protection Act 1998.

III. ACCESS AND BENEFIT-SHARING: APPROVALS, APPROVING AUTHORITIES AND APPLICATION PROCEDURES

States determine the conditions upon which access to their genetic resources may be granted in the exercise of their sovereign rights over their natural resources. The prior informed consent of the provider country is required. The terms for the access are reflected in an agreement, or a permit, that sets out the MATs. This section of the document examines types of approvals, approving authorities and application procedures. Subsequent parts review other important requirements relating to benefit-sharing as well as the other specific conditions and the conditions for approval.

1. Access: types and stages of approval

Under the CBD, authorization or approval for access must be secured from the Contracting Party - the state - based on Article 15.5. This is referred to as prior informed consent (PIC). The Bonn Guidelines adopt the same formulation. However in some laws, the term 'PIC' refers, either exclusively or additionally, to the consent that the state requires the applicant to obtain from the relevant stakeholders, such as ILCs, private land owners, the local authority or the lead agency.[183] The consent by the state is given in the form of a permit or a license. Sometimes it is incorporated in an agreement between the state and the applicant.

In several countries, PIC is given in the form of a certificate or other standard form.[184] Some other countries require that the PIC be given in the form of a contract or agreement.[185]

The number of agreements and consents required depends upon the number of layers of approving authorities and persons from whom consent must be sought.[186] Often, as well, a separate authorization is mandated in respect of access for different purposes, such as for research or commercialization. Thus, there may be a several inter-related agreements for any single access authorization. This indeed appears to be the norm.[187]

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[183] This is elaborated later Chapter IV, paragraph 2(c) and paragraph 4.

[184] **Philippines** (PIC Certificate to be issued in the standard form set out in Annex 4 of the Guidelines), **Uganda** (PIC will be granted in the Form set out in the Second Schedule).

[185] **Bolivia** (Accessory Contract and Annex), **Vanuatu**, **Costa Rica** (Model contract prepared by Technical Office), **Australia** (Benefit-sharing agreement which is a registered indigenous land use agreement under the Native Title Act 1993), and **Guyana** (The draft Regulations provide that where the access application is in respect of private lands, the applicant shall submit a copy of an agreement from the owner or occupier of the lands together with the application. It should be noted that at the draft Regulations also set out several issues for consideration by the EPA, including the question of whether a PIC certificate should be issued when the application is submitted).

[186] See later discussion under paragraph 2(b)(ii) 'No single focal point: multiple authorities'.

[187] Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors*, CBD, UNEP, 2008 at p. 28-29: note that bioprospecting rarely involves a single, framework agreement. An inter-locking web of agreements between various parties is the norm. Even attempts to make a single umbrella agreement, as in the case of the University of Illinois- Chicago Vietnam Laos Program, ended up developing 3-7 different agreements that function in inter-locking ways. 'Often they result in a sort of web, but sometimes a more hub and spoke format' (quoting an official involved in the Program).

For some countries, access is provided through a single agreement.[188] Some countries require a single access permit or other similar authorization referred to by different nomenclatures.[189] Several countries require an access permit[190] together with the relevant benefit-sharing and/or material transfer agreement.[191] For countries governed by the **Andean Decision 391**, the ABS framework involves more than one agreement: Access Contract together with Accessory Contract and an Annex.[192] Some require an access permit together with the written permission of the access provider.[193] Some attach a condition to the access permit such as requiring the holder of the permit to facilitate the active involvement of the provider's citizens and institutions in the activities as part of the benefit-sharing. But it does not state that this must be through an agreement.[194]

Almost all countries require MATs for access. This implies the conclusion of an agreement between the States. Some countries do not expressly use the term 'MAT' but use a different nomenclature. However, much the same position remains, as the applicant must enter into an ABS agreement with the relevant stakeholder(s).[195]

Some countries require MATs to be negotiated.[196] In some regional and national laws, the terms for the access are not mutually agreed but are conditions imposed on the resource user.[197] Several countries set

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[188] **Guyana** (Research Agreement), the **Philippines** (for bioprospecting - a single Bioprospecting Undertaking which incorporates negotiated benefit-sharing terms in addition to standard terms and conditions), **Bangladesh** (for national scientific research - a research agreement; for commercial purposes, an access agreement), **Ethiopia** (access agreement), **Malawi** (a single Research and Material Transfer Agreement), and **India** (written agreement for access by foreigners. Locals are only required to give prior intimation to State Biodiversity Board, in such form as may be prescribed by the state Government).

[189] **Brazil** (for Brazilian institutions or universities - special authorization), **Costa Rica** (*in situ* genetic resources - access passport), and **Sabah** (access license).

[190] Bonn Guidelines allow access to be granted by issuing a permit or license or following other appropriate procedures – Article 39.

[191] **Bhutan** (access permit, and material transfer agreement/contract agreement), **Uganda** (an access permit, together with accessory agreement with affected parties together with material transfer agreement with the government), the **Philippines** (for non-commercial scientific research - an Affidavit of Undertaking or a Memorandum of Agreement together with a Gratuitous Permit), **South Africa** (a bioprospecting permit, integrated bioprospecting and export permit or export permit for research purposes other than bioprospecting together with a benefit-sharing agreement and, where applicable, a material transfer agreement), **Australia** (for commercial purposes, access permit together with a benefit-sharing agreement), the **Northern Territory** (access permit together with a benefit-sharing agreement), **Queensland** (collection authority together with a benefit-sharing agreement), **Brazil** (for commercial purposes - authorization together with a benefit-sharing contract known as the Contract for Use of Genetic Heritage and Benefit-Sharing), **Costa Rica** (*ex situ* collections - access permit together with a material transfer agreement), **Hawaii** (access permit together with an ABS agreement and, where applicable, a material transfer agreement), **Pakistan** (permission to access together with benefit-sharing agreement), and **Vanuatu** (bioprospecting permit together with a contract concluded with custom landowners or owner of TK).

[192] See example **Bolivia** and later discussion on Chapter IV Paragraph 5(a) 'Mutually Agreed Terms (MATs).

[193] **Australia:** This is for access for non-commercial purposes where an access permit together with the written permission of the access provider is required to enter, take and remove samples from the biological resources of the area.

[194] **Kenya.**

[195] **Hawaii**.

[196] **Bolivia, Brazil, Costa Rica, India, Pakistan, Uganda, Vanuatu, Queensland** (In the form of benefit-sharing provisions. See section 33 of the Queensland Biodiscovery Act 2004)**, Northern Territory, Bangladesh, Afghanistan,** and **Malawi**.

[197] **African Model Law** (An agreement between the NCA and the applicant which contains commitments undertaken or to be undertaken by the collector; hence, these terms are not mutually agreed but are conditions imposed upon the collector prior to granting of access by the NCA), **Bulgaria** (The terms and procedure for provision of access to genetic resources shall be established by a regulation adopted by the Council of Ministers), **South Africa** (In material transfer agreements and must be in the prescribed format and contain the information specified in the South African Biodiversity Act 2004).

out minimum terms which must be contained in access agreements, but leave room for the parties to negotiate further terms or for the authority to impose additional terms.[198]

Most countries require that the PIC of relevant stakeholders be obtained before access can be granted.[199] Some countries merely require that stakeholders be consulted before a decision for access is made;[200] the manner of this consultation is not specified although some countries require a meeting to be held for this purpose.[201] The object is to ensure that there is a process to establish that consent is sought and properly given. For this reason there are elaborate procedures to ensure this consultation with stakeholders.[202]

2. Authorities: National competent authority (NCA) an overview

The application for access must be forwarded to some authority in the state. It decides on the application. This will be the focal point or body designated by the state – usually referred to as the national competent authority (NCA). The NCA may require the applicant to seek the consent of others who have a stake in the resource in some way. The particular stakeholder is usually determined by reference to his relationship to the resource, usually his rights over, or in relation to, the land where the resource is located; or by reference to the 'ownership' of the knowledge related to the genetic resource (creator, holder, custodian, community ownership). If the resource is located upon private land, then the consent of the land owner, or sometimes occupier may be required. Where the resource is on land held by ILCs, then their consent may be required. Sometimes the application is made exclusively and directly to the owner of the land where the resource is located, without reference to a state authority.[203] Usually though, the NCA maintains an overall supervisory role in regulating access.

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[198] **Ethiopia** (Provides for minimum content of access agreements to be imposed by the Institute of Biodiversity Conservation; however, the kind and amount of benefit to be shared shall be determined on a case by case basis in each specific access agreement), **Bhutan** (Sets out several conditions for benefit-sharing, one or more of which are required to be included in the MTA or Contract Agreement to be signed between the Competent Authority and the applicant), **Guyana** (Under the Guyana Draft Regulations 2001, every Research Agreement is to be in the prescribed form and to contain minimum terms. The Guidelines for Biodiversity Research set out terms which every Research Agreement must contain, but does not indicate whether these terms are exhaustive or whether other terms can be negotiated or imposed), **Nigeria** (Resource users are required to give certain undertakings, including an undertaking to share benefits derived from the resources with the Government and people of Nigeria; however, the exact terms of such benefit-sharing are not prescribed), **Philippines** (Bioprospecting Undertaking to contain standard terms and conditions as listed in Annex I, in addition to negotiated terms of benefit-sharing), **South Africa** (Benefit-sharing agreements must be in the prescribed format and contain the information specified in the South African Biodiversity Act 2004, in addition to any other matters that may be prescribed. Parties are free to determine benefit-sharing terms, although the Bio-prospecting, South African ABS Regulations 2008 provides lists of possible benefits that may be shared).

[199] **Bolivia, Brazil, Costa Rica, Hawaii, Pakistan, Uganda, Vanuatu** (By inference, as 'PIC' is not mentioned in the ABS law of Vanuatu. However, the resource user is required to conclude a contract with the relevant custom landowners or owners of TK concerning rights of access, rights of acquisition of any biological resource or TK, and benefit-sharing. See section 34, Vanuatu Environmental Act 2002), **Australia** and the Australian states of the **Northern Territory** and **Queensland.** This necessarily implies that the PIC of the state should be obtained before access can be granted **Bangladesh, Afghanistan, Bhutan, Ethiopia, Malawi, Bulgaria, Nigeria, Kenya, Philippines** and **South Africa**. The same requirement is imposed by several regional laws: the **ASEAN Framework Agreement** and the **African Model Law**. This is in accordance with Bonn Guidelines. The Guidelines recognize the importance of the relevant stakeholders, including ILCs, to be consulted, when determining access and their consent should be obtained. – Article 18 and 26(d).

[200] In **India**, the NBA has to consult with the concerned local bodies before making a decision on the application for access: Rule 14(3) of the Indian Biodiversity Rules 2004. Other stakeholders (local bodies and other benefit claimers) only come into the picture when the NBA determines the quantum of benefits to be shared: Rule 20(5). **Philippines** (resource user to request Protection Areas Management Board, barangay or tribal council to call for community assembly; PIC to be issued within 30 days after the consultation).

[201] **Guyana.** Regulation 10(2) of the Guyana Draft Regulations 2001.

[202] **Philippines** (resource user to request Protection Areas Management Board, barangay or tribal council to call for community assembly; PIC to be issued within 30 days after the consultation). See elaboration later Chapter IV paragraph 4.

[203] USA and Canada are examples.

2.1. NCA granting access approval and its role

The NCA is variously constituted in the different countries surveyed. In some an existing organization or authority assumes the role; in others an entirely new body is created. Some countries have more than one authority in charge;[204] some create a new authority within an existing body.[205] Some countries appoint a general environmental body.[206] Others create a specific body to address biodiversity matters;[207] while yet others establish a specific body to address ABS issues only.[208] So long as a single body or focal point is designated, the choice of the particular structure of the NCA poses no particular problem for the application for access. The converse may be true where permission has to be sought from several bodies. This, coupled with the process for securing PIC and MATs from several stakeholders poses serious obstacles to obtaining access.[209]

2.2. Single focal point or NCA

For some countries there are different single focal points depending upon whether the access is for bioprospecting or for export for research.[210] Differently named single focal points exist in different countries: National Environment Protection Agency,[211] Biodiversity Council,[212] National Council for Science and Technology,[213] Biodiversity Advisory Council,[214] CEO of the Agency administering the Act[215] and Environmental Protection Agency (EPA) Chief Executive,[216] Institute of Biodiversity Conservation[217] and National Biodiversity Authority (NBA).[218] There are slight variations.[219]

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[204] **Philippines.**

[205] **Panama.**

[206] **Afghanistan, Kenya, Nicaragua.**

[207] **Costa Rica, Ethiopia, India, Vanuatu.**

[208] **Brazil.**

[209] One of the most common problems associated with accessing genetic resources cited by German companies in one study was the absence of appropriate focal points: Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors*, CBD, UNEP, 2008 at p. 24, citing Holm-Muller et al, *Users of Genetic Resources in Germany: Awareness, Participation and Positions regarding the Convention on Biological Diversity*, Federal Agency for Natura Conservation (BfN), Bonn-Germany: Skripten 126.

[210] **Kenya, South Africa.**

[211] **Afghanistan.**

[212] **Sabah.**

[213] **Uganda.**

[214] **Vanuatu.**

[215] The Australian state of **Northern Territory.**

[216] The Australian state of **Queensland.**

[217] **Ethiopia.**

[218] **Bangladesh. In Costa Rica,** there is only one focal point, the Technical Office of National Commission for the Management of Biodiversity (CONAGEBIO) within the Ministry of Environment and Energy (MINAE). The interested party registers with this Technical Office which then issues a preliminary identity card as potential user.

[219] In **Bhutan** the NCA – which represents the national interests as well as that of the communities harbouring, cultivating, developing and maintaining the resource - designates a single agency which is then responsible for processing the application. And also for monitoring the permits granted – see later under Chapter V, paragraph 1**.**

Final approval still vests with the NCA. **Pakistan** has a single focal point, the NCA, which grants approval after the PIC is obtained from the State in whose jurisdiction the genetic resource is accessed. **Nigeria** permits the prospecting of genetic material and the removal of biological material from National Parks only upon the written PIC of the Minister on the recommendation of the National Park Service. Section 36(1) Nigerian National Park Decree 1999.

2.3. No single focal point: multiple authorities220

In several other countries, the access process appears to be complicated by the need to apply to several bodies.[221] In some countries, the procedures for access are elaborate and involve multiple authorities.[222] Some countries have problems in demarcating the authority in a federal type constitutional structure.[223]

In some countries, there are several bodies involved in approving the application.[224] In some others, applications for access are submitted to a different body depending on whether the applicant is a foreigner or a national.[225] Some countries stipulate different procedures for nationals and foreigners.[226]

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[220] Bonn Guidelines suggest Parties to designate only one national focal point for ABS – Article 13, but the Guidelines allow more than one competent national authority to be responsible for granting access – Article 14 and that the competent national authority/authorities that has/have the legal power to grant PIC may delegate this power to other entities – Article 15.

[221] An example is **Guyana**. There are three bodies involved under the Guidelines: the NCA (National Biodiversity Advisory Council), the government (with whom a research agreement is signed before commencing the research) and the EPA (which then secures the permit for field work. Under the proposed draft regulations, the parties involved are the EPA (the application for the research agreement made), and the land owners/occupiers (for consent where the resource is located on private lands) and the ILCs (if the resource is located within their areas).

[222] In the **Philippines,**: the Secretary of the Department of Agriculture and/or Department of Environment and Natural Resources; Section 6.1 of the Philippines Guidelines for ABS 2005. and the Chairperson of the Palawan Council for Sustainable Development (for bioprospecting in the Province of Palawan), co-sign the agreement referred to as a Bioprospecting Undertaking. Section 6.1 of the Philippines Guidelines for ABS 2005.

[223] In **Brazil,** there seems to be some uncertainty in the demarcation of authority between the State and the Federal authorities. The Federal Government authorizes the access on the basis that genetic heritage is its patrimony. Article 2 of the Brazilian Provisional Act requires access to genetic heritage (including PGRFA) to be authorized by the Federal Government. The Act does not identify the ownership of genetic heritage, neither is it stated expressly in the Constitution as belonging to the Federal Union. According to Article 225 of the Federal Constitution of Brazil, genetic heritage are described as the heritage and patrimony of the Federal Government. See Andre Lima, *Ownership of Genetic Rights: from whom? For whom?* Online: http://www.socioambiental.org/pib/english/rights/patrgeni.shtm.

However, two other states make a similar claim. States of Amapá and Acre. Article 2 of the State of Amapá – Access Law N°0388/97.An applicant for access to genetic resources located in these states, would be placed in an invidious position of deciding the applicable law.

The application in cases involving federal jurisdiction is made to a Council established under the Ministry of Environment; or, to a body responsible for the Brazilian scientific and technological research policy (if there is participation of a foreign entity); or an accredited institution (to authorize another Brazilian institution that carries out research and development in biological and related areas for particular activities).

[224] In **Malawi,**: Affiliating institutes, certifying institutions and the National Research Council. The research application is reviewed by the Institutes before submission to the National Research Council. The certifying institutions are essentially the relevant governmental authority in charge of the sector from where the genetic resource is to be accessed. Upon approval by the National Research Council the certifying institutions issue a certificate of approval to the applicant. For **Hawaii,** there are two bodies to whom an application is made: the Commission on Bioprospecting for review and recommendation prior to going to the Department of Land and Natural Resources (where there is an intent to produce a commercial product or process); and directly on a fast track to the Department (where the purpose is conducting academic or scientific research that does not infringe on the knowledge, innovations, traditional or customary practices of Hawaiians): Section 6.1, Hawaiian Draft Bill on Bioprospecting 2007.

[225] In **Bolivia,** Foreigners seek approval from the Competent National Authority; so do nationals if the access is in the jurisdiction of more than 1 Department. In all other cases, nationals can go either to the Departmental or the Competent National Authority. Prefectures also have the power to receive applications.

[226] **India:** For foreigners, approval is from the NBA regardless of the purpose. Citizens and companies/associations and other organizations registered in India for commercial purposes need only give prior intimation to the State Biodiversity Board. The Biodiversity Management Committees form the third-tier of the institutional structure of the Authority at the local/ village level. It will be consulted by the NBA and the State Biodiversity Board on any decision regarding access and use of biodiversity within its jurisdiction. Note that collaborative international research projects involving transfer or exchange of biological resources or information between institutions that are approved by the Central government and abide by its guidelines are exempted from the approval process. Foreigners are the following under Section 3(2) of the Indian Biodiversity Act 2002. '(a) a person who is not a citizen of India; (b) a citizen of India, who is a non resident as defined in clause (30) of section 2 of the Income tax Act, 1961;

3. Parties to MAT and PIC

There are a range of parties[227] with whom the applicant may have to negotiate the MATs. They include:

- The state – represented usually by the NCA and/or lead agency,[228] or a Minister of the relevant ministry;[229]
- Owner or provider of the resource and/or of the land on which the resource is located;[230]
- Owner or provider of associated knowledge and/or intangible components associated to the genetic resources;[231]
- Local and indigenous communities or their representatives;[232] and National research or scientific institutions.[233]

There are some variations.[234] There are a large range of bodies and officials identified as stakeholders from whom PIC must be obtained.[235] These include the following:

(c) a body corporate, association or organization;

(i) not incorporated or registered in India; or

(ii) incorporated or registered in India under any law for the time being in force which has any non Indian participation in its share capital or management.'

[227] Bonn Guidelines address this specifically in terms of the parties with whom benefits are to be shared pursuant to the MAT, to include governmental, non-governmental or academic institutions and ILCs - Article 47. The importance of the relevant stakeholders to be consulted when negotiating and implementing MATs and in the sharing of benefits is also recognized – Article 18.

[228] **Bolivia** (MATs to be negotiated in Access Contract with the competent national authority, i.e. the Under-Secretary's Office of Natural Resources), **India** (MATs to be negotiated with the Authority in consultation with local bodies and benefit claimers), **Pakistan, Uganda** (accessory agreement and material transfer agreement to be negotiated with lead agency), **Northern Territory** (CEO of the Agency administering the Biological Resources Act 2006), **Bhutan, Bangladesh** (National Biodiversity Authority), **Afghanistan** (National EPA), **African Model Law, Guyana** (under the Guidelines for Biodiversity Research, the Government of Guyana; under the draft Environmental Protection (Bio-prospecting) Regulations 2001, the EPA), **Philippines** (Bioprospecting Undertaking to be entered into between the applicant and the implementing agencies concerned).

[229] **Australia**, **Queensland** (DSDI Minister, i.e. the Minister responsible for administering the Gene Technology Act 2001)

[230] **Uganda** (accessory agreement to be negotiated with the owner), **Vanuatu** (MATs to be negotiated with custom landowners), **Philippines** (benefit-sharing arrangements to be negotiated between applicant and resource provider, to be incorporated into the Bioprospecting Undertaking).

[231] **Bolivia** (MATs to be negotiated in Annex with supplier of the intangible component associated to the genetic resource), **Vanuatu** (MATs to be negotiated with owner of TK)

[232] **Costa Rica** (MATs to be negotiated between the applicant and parties involved in access and conservation of biochemical and genetic resources, be it individuals or institutions registered for that effect, particularly local communities and indigenous people), **Uganda** (accessory agreement to be negotiated with local community), **South Africa**.

[233] **Costa Rica** (MATs to be negotiated between the applicant and parties involved in access and conservation of biochemical and genetic resources, be it individuals or institutions registered for that effect; in practice, many of the agreements have been concluded between the applicant and the National Biodiversity Institute. See Santiago Carrizosa, *'Diversity of Policies in Place and in Progress'*, Accessing Biodiversity and Sharing the Benefits: Lessons from implementing the Convention on Biological Diversity, IUCN Environmental Policy and Law Paper No. 54, 2004, p 110 - 113), **Malawi** (National Research Council of Malawi), **Ethiopia** (Institute of Biodiversity Conservation).

[234] In **Brazil**, MATs are to be negotiated between on the one hand, the owner of the public or private area or the representative of the indigenous community and the official Indian Affairs body, or the representative of the local community - and on the other, the Brazilian institution authorized to carry out the access and the recipient institution: Article 27 Brazilian Provisional Act 2001. In **Hawaii**, the applicant must enter into ABS agreements with all the stakeholders: landowners, Hawaiians (as defined by section 10-2 of the Hawaiian Draft Bill for Bioprospecting 2007), community from where the resources are sampled, researchers, universities, and the biotechnology industry.

[235] These bodies or person are also set out in Articles 28 to 32 of the Bonn Guidelines.

- The government (including different levels: national/provincial/local) through its NCA and/or relevant lead or designated agency;[236]
- Local and indigenous communities and/or their representatives;[237]
- Owner of the land on which the resources are located;[238]
- Owner or provider of the resources;[239]
- Owner or supplier of associated knowledge or intangible components, where applicable;[240]
- National research, scientific or similar institutions;[241]
- NCA and/or the body in charge of *ex situ* collection centres, for *ex situ* collections;[242]
- Body in charge of protected areas, for protected areas;[243]
- The maritime authority;[244] and
- Other interested persons and/or bodies.[245]

Sometimes the PIC must be obtained from one body or authority;[246] other times it must be obtained from more than one body or authority.[247] Some countries require a range of stakeholders from whom consent

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[236] **Pakistan, Uganda, Queensland, Northern Territory** (CEO of the Agency administering the Act), **Bhutan**, **Bangladesh, Malawi** (the authorities whose jurisdiction under which the resources fall), **African Model Law** (NCA to consult with local communities in order to ascertain that their consent has been sought and granted), **Kenya**.

[237] **Bolivia, Brazil, Costa Rica, Hawaii, Pakistan, Afghanistan, Uganda, Bhutan** (the Head of the Ministry of Agriculture representing the interest of the local communities), **Bangladesh, Ethiopia, African Model Law** (NCA to consult with local communities in order to ascertain that their consent has been sought and granted), **Philippines**.

[238] **Bolivia, Brazil, Costa Rica, Hawaii, Uganda, Vanuatu** (PIC is not mentioned in the ABS law but there must be a contract concluded with custom landowners or owners of TK concerning rights of access, rights of acquisition of biological resources or TK, and benefit-sharing), **Afghanistan, Guyana** (PIC not specified under the Guidelines for Biodiversity Research; under the draft Regulations, where the application for access is in respect of private lands, PIC is required from the owners or occupiers), **Philippines** (private landowners).

[239] **Bolivia, Uganda, ASEAN Framework Agreement, Nigeria** (any Nigerian citizen, group or association who owns or has in its possession or custody the genetic material or associated knowledge concerned), **South Africa, Northern Territory** (if the biological resources are in an area which is Aboriginal land and the resource access provider is a Land Trust, the responsible Land Council must consult with the traditional owners of the land).

[240] **Bolivia, Brazil, Vanuatu** (PIC is not mentioned in the ABS law but there must be a contract concluded with custom landowners or owners of TK concerning rights of access, rights of acquisition of biological resources or TK, and benefit-sharing), **Bhutan, South Africa**.

[241] **Bolivia, Ethiopia, Kenya** (a research clearance certificate from the National Council for Science and Technology is required).

[242] **Bolivia, Costa Rica**.

[243] **Bolivia, Brazil**.

[244] **Brazil** (when the access takes place in Brazilian jurisdictional waters, on the continental shelf and in the exclusive economic zone), **Costa Rica** (coastal-marine area).

[245] **Brazil** (the National Defence Council, when the access takes place in an area essential for national security; the competent body when access is for an endemic or endangered species), **Costa Rica** (the Regional Council or the corresponding Conservation Area Director for public roads and sidewalks, or in rivers, lagoons and wetlands), **Hawaii** (researchers, universities and the biotechnology industry), **Kenya** ('interested persons'), **Philippines** (requires PIC from the local community, local government units or other agencies having special jurisdiction over specific areas under existing laws, including the PCSD where bioprospecting activities are to be carried out in Palawan).

[246] **Queensland**: The EPA Chief Executive.

[247] **Bolivia** (The National Support Institution and the owner of or other body having control of the resource or the area in which the resource is located), **Hawaii** (Stakeholders, namely landowners, Hawaiians, community from which the resources are sampled, researchers, universities and the biotechnology industry), **Pakistan** (The State, the Competent National Authority and

must be obtained depending on a mix of criteria.[248] Furthermore, if access to more than one resource is sought, or the resource is located in more than one area, the PIC of each owner or entity having control may have to be obtained.

Some countries however require only for stakeholders to be consulted before a decision for access is made.[249] In addition, in some jurisdictions, genetic resources are said to be 'owned' by the state. In the **Andean** countries, these are considered the 'national patrimony' of the state and are declared to be 'inalienable and imprescriptible'. This implies that the final authority for approval of access to genetic resources rests with the state. The PIC of the state must then be obtained. The land owner has some limited rights – for example the right to benefits if he has nurtured the resource. In **Bangladesh** the state acts as the co-owner of the biological and genetic resources.[250]

As noted the stakeholder from whom access approval is required is determined by reference to his relationship to the resource – as owner, occupier or person in control of the land on which the resource is located; or the person or community that 'owns' or is the custodian of the associated TK. Yet determining

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the local communities concerned), **Uganda** (The lead agency, the local community or owner of the land on which the resources are located. It is unclear whether PIC must be obtained from the lead agency at all times in addition to the PIC of the local community or owner of the land), **Kenya** (The National Council for Science and Technology, interested persons and relevant lead agencies), **Bangladesh** (National Biodiversity Authority and the communities concerned), the **Northern Territory** (The CEO of the Agency administering the Act, the resource access provider (where the access provider is not the Territory or a statutory corporation) the traditional owners of the land (where the resource is in Aboriginal land and the access provider is a Land Trust)).

[248] **Brazil** (The indigenous community - when access occurs in indigenous lands; the competent body - when access occurs in protected areas; the owner of the private area - when access occurs in a private area; the National Defence Council - when access occurs in an area essential for national security; the maritime authority - when the access takes place in Brazilian jurisdictional waters, on the continental shelf and in the exclusive economic zone), **Costa Rica** (**INCOPESCA** - for coastal-marine areas; Regional Council or Conservation Area Director - for public roads, sidewalks, rivers, lagoons and wetlands; authorities of the local communities or indigenous peoples - for indigenous territories; landowners; owners or persons responsible for materials kept in *ex situ* conditions), **Guyana** (under the Guyana Draft Regulations: The various stakeholders namely private landowners and/or ILCs depending on the area in the bioprospecting is to be conducted), **Nigeria** (The Nigerian citizen, group or association owning, possessing, or having in its custody the genetic material concerned or indigenous knowledge relating thereto), the **Philippines** (The resource provider concerned, including indigenous peoples, protected area management boards, local government units, private individuals or other agencies having special jurisdiction over specific areas. Where bioprospecting activities are carried out in Palawan, the resource user must additionally obtain clearance from the PCSD), **South Africa** (The provider of the resource concerned and/or the indigenous community whose traditional use or knowledge of the resource is to be used for the project), **Afghanistan** (The owner of the land - for private land; consent of the relevant group or community - for nomadic land), **Bhutan** (The Head of the Ministry of Agriculture - generally; traditional owners - where access to TK for non-customary uses is sought), **Australia**, **Ethiopia** (Institute of Biodiversity Conservation - access to genetic resources; local community - community knowledge), **Malawi** (The communities/authorities under whose jurisdiction the resources fall), the **African Model Law** (The relevant local community), **ASEAN Framework Agreement 2004** (The party providing the biological and genetic resources).

[249] In **India**, the NBA has to consult with the concerned local bodies before making a decision on the application for access: Rule 14(3) of the Indian Biodiversity Rules 2004; other stakeholders (local bodies and other benefit claimers, including ILCs) only come into the picture when the NBA determines the quantum of benefits to be shared: *Ibid,* Rule 20(5). So it dispenses with obtaining the PIC of ILCs on the basis that their rights are thus protected because they are consulted when benefit-sharing arrangements are discussed. **Guyana** does not expressly require that PIC be obtained from local and indigenous communities in whose areas bioprospecting is to be carried out. Instead, the EPA is to summon a meeting of those communities: Regulation 10(2) of the Guyana Draft Regulations 2001, lay the application before them and explain it in language fully understandable to them: *Ibid,* Regulation 10(4), and to deposit the report of the meeting in specified public places: *Ibid,* Regulation 11(1) for inspection for a period of 14 days: *Ibid,* Regulation 11(2). Within that period, any member of a local and indigenous community in that area may address a letter of protest to the EPA: *Ibid,* Regulation 11(3). The EPA may grant access only when satisfied that any local and indigenous community that may be affected has been consulted: *ibid,* Regulation 14(1)(d), and in making its decision, must have regard to the report of the meeting and the letters of protest: *Ibid,* Regulation 15(1).

[250] Article 8(2) Biodiversity and Community Knowledge Protection Act 1998. Access authorization must be obtained from the NBA: Article 13(4).

the 'ownership' of a resource raises some complex conceptual issues. The term embraces a new legal concept and establishing a legal right to such genetic resources may be problematic.[251] Rights to tangible and intangible property are easily established. Property rights are evidenced by title deeds, or sometimes by actual possession. Intangible property rights, such as IPRs, have an identified inventor who is granted a right. The same, however, cannot be said of a genetic resource that resides within the DNA of living matter. There is neither actual possession nor any indicia of title. There can be no identification by written description; nor indeed can an original owner be established. This problem is exacerbated in relation to naturally occurring genetic resources. Complications could arise if the genetic resource is spread over a large geographical area or is endemic to areas that cut across borders, although in the case of domesticated, as distinct from wild, resources this may not be a problem, as such.

In that case, the consent of the owner of the resource must be sought. In either case, identifying the nature of that right then becomes crucial before provisions on access and benefit-sharing can be adopted. For present purposes, in some cases, particularly for access to wild resources, it may make it difficult to establish with ease and confidence the person or entity from whom the consent must be sought. This could increase the uncertainty of the access, be time consuming and increase transaction costs for the access.

4. Conclusions

To the extent that ABS laws cover GRFA, the ease with which these resources can be accessed will have a direct impact upon the research and development of the resource for food and agriculture. Generally, the laws require approval from a large number of (state) authorities. In addition the PIC of a large number of stakeholders is also mandated. Some of these stakeholders are not easily ascertainable. In addition, or in lieu, MATs for the access are also required to be negotiated either with the state or, in addition or in lieu, with the stakeholders concerned. This multilayered authorization seems to unduly burden access for GRFA. Furthermore, requiring separate approval and from different authorities for research and commercial use may be superfluous in the case of GRFA. This is because commercial use is usually intended from the outset.

It is noted that although several authorities are involved or consulted in the decision-making process, very few of the laws involved authorities responsible for food and agriculture. It is notable that in none of the laws was the direct approving state authority a ministry or agency involved in food and agriculture.[252] This is surprising as it is predictable that there could be a large number of accessions of GRFA.[253] The absence of their involvement may mean that food security concerns may not be adequately reflected in the implementation. Their active involvement may also have resulted in the inclusion of provisions that emphasises that in respect of the exchange of GRFA, there are established systems that should not be complicated by additional ABS procedures and requirements. The fact that the laws of almost all countries include domesticated genetic resources in the scope of their ABS laws suggests that the existing realities and the practical difficulties of this inclusion may not have been duly taken into account.

Finally, it is self evident that the establishment of a single or easily identifiable approving authority facilitates the processing of access applications. As is frequently suggested in debates on ABS, multiple permit requirements involving several authorities contributes to inefficiency and ineffectiveness of the

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[251] Morten Tvedt and Tomme Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD,* IUCN Environmental Policy and Law Paper No. 67/2, ABS Series No.2, 2007, at p. 7.

[252] In **Bhutan,** the head of the Ministry of Agriculture represents the interests of the local communities.

[253] Just as an illustration, the number of possible rice accessions is estimated at 1.2 million

authorization process. For the food and agriculture sector this is particularly detrimental as the free access to and exchange of GRFA is unduly impeded.

IV. ACCESS AND BENEFIT-SHARING: APPLICATION PROCEDURES - REGULAR/ SIMPLIFIED PROCEDURES (DEPENDENT ON PURPOSE OF ACTIVITY/USE OF STANDARD APPLICATION FORM)

Many countries, although not providing exemptions for access to genetic resources for research,[254] nonetheless provide for differentiated – usually less onerous - access procedures for non-commercial purposes, including research, academic or conservation purposes.[255] These contrast with the procedures for access for commercial, or potential commercial purposes.

Some countries provide less onerous access procedures for national public research and local institutions of higher learning.[256] Some even allow public universities to establish their own controls and regulations for non-commercial projects.[257]

The Bonn Guidelines propose facilitated acquisition of material for systematic use which is for taxonomic research as specified in the Global Taxonomy Initiative.[258]

One way of ameliorating the application of the onerous conditions so as to facilitate access to the use and exchange of GRFA, if there are no exemptions from these procedures for such use, is to provide softer or fast track procedures for access for non-commercial purposes. However a credible mechanism will need to be established for verifying that access which starts off with a non-commercial purpose does not end up in the commercial sector. Further, such procedures could apply as well to genetic resources that are mediated through market-based commercial transactions. This would be particularly applicable in the case of livestock and commodities. Some countries, as noted earlier, provide specifically for exemptions for commodities.

Some countries prescribe a standard application form for access which is annexed to the relevant legislation.[259] Others do not prescribe a standard application form, but set-out in detail all the information to be provided in completing the application form and the technical guidelines.[260]

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[254] **Costa Rica, Guyana, Nigeria, Queensland, Northern Territory** and **South Africa.**

[255] **Australia**, **Bhutan** (procedure not specified), **Bangladesh**, the **Philippines**, **South Africa** and **Hawaii**. Access for non-commercial purposes may be described by different names in the laws of different countries. Bangladesh refers to access for 'national scientific research'; the Philippines refers to the collection and utilization of resources 'for scientific research and not for commercial purposes'; South Africa refers to 'research other than bioprospecting'; **Hawaii** refers to 'academic or scientific research that does not infringe on the knowledge, innovations, traditional or customary practices of Hawaiians'. In **Guyana,** the non-commercial collections may be used only for taxonomic, conservation, ecological or bio-geographic investigations: regulation 4(7) of the Draft Regulations 2001.

[256] **Ethiopia** (also: intergovernmental institutions based in Ethiopia), **Brazil** (includes private Brazilian institutions, both public and private, that carry out research and development in biological and related areas, and Brazilian universities, both public and private).

[257] **Costa Rica.** They can do so, otherwise they will have to comply with the law in the same way as commercial bioprospectors: Article 4 Transitory of the Costa Rican Biodiversity Law 1998. Public universities and other institutions can also periodically subscribe to framework agreements with the authority to process the access permits and reports of operations: Article 74 of the Costa Rican Biodiversity Law 1998. It is interesting to note that in the Costa Rican Rules for Access 2003, Article 21 makes clear that the framework agreement can be subscribed for basic research, bioprospecting or economic exploitation.

[258] Article 11(l). Special terms and conditions should be established under MATs to facilitate taxonomic research for non-commercial purposes: Article 16(b)(viii).

[259] **Bolivia** (Annex I to Bolivian Regulations on Access 1997), **Guyana** (under the draft Regulations: First Schedule to the Guyana Draft Regulations 2001), **Kenya** (First Schedule to the Kenya ABS Regulations 2006), **Philippines** (Section 8.1(c) of the Philippines Guidelines for Bioprospecting 2005), and **Australia** (Applications for permits for access to biological resources in

Some countries prescribe a standard/model material transfer agreement (MTA) for access to genetic resources.[261] Some countries make access conditional upon certain standard conditions.[262]

In some countries, the standard conditions are mandatory but non-exhaustive, meaning that the parties are free to negotiate other conditions or the authority is entitled to impose other conditions in addition to the standard conditions.[263] Some countries merely set out the standard undertakings, which persons seeking access must give, but do not state expressly that other conditions can be negotiated or imposed.[264]

Standard forms and conditions simplify authorization procedures especially where there is a large number of accessions and clearly defined end-uses. It facilitates free use and exchange of GRFA. For this reason, the ITPGRFA provides a standardized accession procedure or SMTA for specific uses of a defined number of crops and forages. This facilitates access because of the many accessions.

1. Differentiated procedure for foreigners and citizens[265]

Several countries specify different access procedures for foreigners compared to nationals.[266] In some countries, foreigners are required to obtain access approval from a different body.[267]

The relaxation of procedures for nationals, especially for access for research purposes, may serve the national interest. It could, for example, engender research in respect of genetic resources within national boundaries and promote national resilience in meeting the needs of society and in particular be aimed at nurturing domestic production to enhance food security.

However, if there is a high degree of interdependence of a country for its GRFA with other countries, as seems to be the case generally speaking,[268] this may undermine the country's interest if there is no reciprocal system of international exchange of such resources. Indeed it may well be detrimental to the country's long term food security. Developing countries, for example, secure animal germplasm from countries of the North as well as from other countries of the South. This is done through the sale of

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Commonwealth areas can be made online by logging on to a database known as the Genetic Resources Information Database (GRID)).

[260] Costa Rica, Article 9 of the Costa Rican Biodiversity Law 2003.

[261] **Uganda** (standard forms for PIC, accessory contract and MTA), **Malawi** (MTAs to be provided by the National Research Council of Malawi or any of the certifying institutions), **Guyana** (every Research Agreement to be in a prescribed form and to contain minimum terms and conditions), **Philippines** (Bioprospecting Undertaking to contain standard terms and conditions), **South Africa** (MTAs and benefit-sharing agreements to be in prescribed form).

[262] **Kenya** (standard conditions to be implied in every access permit), **South Africa** (standard conditions which must be included in every permit), **Nigeria** (access conditional upon certain undertakings being given).

[263] **Guyana**, **Kenya**, **Philippines**, **South Africa.**

[264] **Nigeria.**

[265] The Bonn Guidelines do not distinguish between foreign users and local users.

[266] In the **Philippines**, different procedures for access for non-commercial scientific research apply to a foreign and a national seeking access. **Guyana**'s Guidelines are to be 'suitably modified' before being applied to nationals wishing to do research on biodiversity in Guyana.[266] However, the nature of such modifications is not specified.

[267] **Bolivia**, **India**. In India, non-citizens, non-residents, bodies corporate, associations or organizations who are not incorporated or registered in India and bodies corporate, associations or organizations which are incorporated or registered in India but have non-Indian participation in share capital or management are required to obtain the approval of a different body. **Brazil** provides for a special procedure for access not associated with bioprospecting which involves the participation of a foreign legal entity. In such cases, the access must be authorized by the body responsible for the Brazilian scientific and technological research policy. All other types of access are to be authorized by the Genetic Heritage Management Council Articles 10 and 12 of the Brazilian Provisional Act 2001.

[268] See earlier discussion Chapter 1, paragraph 8, subheading '*Countries' interdependence'*.

livestock as well as the breeding material (semen) on a commercial basis. The system seems to be working well. It would be counterproductive to this established and time-tested mechanism of exchange which has contributed to the development of improved varieties and added to the stock of food if additional ABS requirements are imposed for the transfer of such material.

2. Public information/participation prior to approval

A number of countries require the application for access to be published or otherwise circulated prior to approval.[269] Some countries require the application to be placed in a public area to enable the public to view it.[270]

The objective for this public consultation, although not stated in the laws, is to ensure that the public is informed of matters relating to the nation's resources and to allow those who could be adversely affected to raise their concerns. If food security is not fully considered within the ambit of the national ABS law, then concerns may be raised that the access would not allow for its realization (for example by eroding genetic diversity and/or by impeding or undermining the free use and exchange of GRFA). Some countries also require an environmental impact assessment (EIA).[271] The EIA is made available to the public for its feedback. However, often no real environmental impact is involved when accessing and exchanging genetic resources from farmers' fields. In such a case, the whole process of providing information, and the concomitant public participation and feedback may not be entirely appropriate. Instead, it makes access unduly cumbersome, delays the approval process and increases transaction costs.[272] In some situations, though, an environmental assessment could well be relevant. The code for collecting germplasm, which limits the amount of genetic/biological resources to collected and where it is collected, may have an impact on the remaining cultivation, biodiversity and the ecosystem.

3. Payment for access costs (project/collecting costs) and administrative costs

Most countries impose payment of administrative costs for the access application.[273] Some exempt such payment where the application is for non-commercial purposes.[274] Some countries do not impose an

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[269] **Bolivia** (The Competent National Authority shall publish a summary in a written and oral medium of communication of national circulation for public consultation. The purpose is to invite persons who can supply additional information or who know of the existence of an impediment to perfect the requested access to submit the same to the Competent National Authority. *See* Article 22 of the Bolivian Regulations on Access 1997), **Kenya** (The application is to be published in the *Gazette* and at least one newspaper with nationwide circulation or in such other manner as may be considered appropriate. The purpose is to invite representations or objections in respect of the proposed access permit. *See* Regulation 10 of the Kenyan ABS Regulations 2006), **Australia** (The Minister to publish on the Internet a notice inviting comments on the proposed access).

[270] **Pakistan** (The completed application is to be placed in a public registry for a period of three months which may be consulted by any person), **Bangladesh** (The application is to be deposited in the Local Government office to be made available to the local communities).

[271] Example **Pakistan,** Article 4(2)(xi), Draft Law on Access and Community Rights, 2004. The application, which includes the EIA, is placed in a public registry for 3 months and may be accessed by any person. Also section 17, **Sabah** Biodiversity Enactment 2000requires a socio-economic assessment. See also **Australia**: Environment Protection and Biodiversity Conservation Regulations 2000, Division 8A.4, Reg. 8A.16(3).

[272] See later paragraph (e), 'Timelines'.

[273] **Sabah (**Section 19 of the Sabah Biodiversity Enactment 2000), **Guyana** (Regulation 4(7) of the Guyana Draft Regulations 2001. The amount varies depending on the type of Research Agreement applied for), **Kenya** (Regulation 9(1) of the Kenyan ABS Regulations 2006), **Philippines** (Sections 8.1(c) and 11.1 of the Philippines Guidelines for Bioprospecting 2005), and **Malawi** (Part D of the Malawi Guidelines for Access. The amount varies depending on whether the applicant is local or foreign and whether the applicant is an academic or research institution, a non-profit institution, or a commercial institution).

[274] **Australia.**

application fee as such, but require the resource user to pay a fee for accessing the resource concerned.[275] Some countries require the payment of administrative rates and similar charges.[276] Some countries make the applicant responsible for the expenses of publication and evaluation necessary for access to genetic resources.[277]

These administrative costs must be distinguished from the costs for the collection of the genetic resources or research with regard to the genetic resources accessed.[278] It may be assumed that other countries require the applicant to bear such costs without making this explicit.

Occasionally, some form of performance bond or security deposit may also be imposed.[279]

Although the rationale for these administrative costs is to help ease the financial administrative burden on provider countries, this must be balanced against the need to minimize bureaucratic hurdles especially when the objective is to facilitate free use and exchange of GRFA to secure food security.

Examples of Potential Impacts of ABS on GRFR:

- High Administration costs.
- Delays in approval
- Uncertainty regarding collection - ownership
- Not respecting existing system, including current commercial exchange that provides in country benefits
- Uncertainty of the need for an EIA

4. Timelines

The discussion thus far shows that applications for access often involves several bureaucratic processes all of which prolong the time it takes to obtain the consent of the state authority for the access to genetic resources. The evaluation or approval of other agencies may be required. Administrative arrangements may need to be made with a designated authority before the collection can be undertaken. Other

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[275] **India** (The Biodiversity Management Committees may levy charges by way of collection fees from any person for accessing or collecting any biological resource for commercial purposes from areas falling within its territorial jurisdiction. See section 41(3) of the Indian Biodiversity Act 2002), **Bangladesh** (The collector is required to pay a fee for commercial collection to be decided by the National Biodiversity Authority. See Article 16(5) of the Bangladesh Biodiversity Act 1998).

[276] **Costa Rica** (Applicants to pay administrative rates or other expenses in accordance with the amounts established by the Technical Office. See article 17 of the Costa Rican Rules for the Access 2003), **Sabah** (Costs and expenses incurred in making an application for the access licence and in complying with the conditions imposed by the Council and the Enactment. See section 19 of the Sabah Biodiversity Enactment 2000). **Guyana** imposes an additional fee when the Research Agreement is executed Regulation 16(5) of the Guyana Draft Regulations 2001. **South Africa** imposes a non-refundable permit fee Annexure I to the Bio-prospecting, Access and Benefit-Sharing Regulations 2008. The amount varies depending on the type of permit obtained.

[277] **Bolivia** (Article 29 of the Bolivian Regulations on Access 1997).

[278] **Bhutan** explicitly requires the applicant to bear all costs relevant to the collection, including costs of participating staff identified by the Competent Authority Section 9 of the Bhutan Biodiversity Act 2003.

[279] **Sabah** (The Yang di-Pertua Negeri may, after consulting the Council, by regulation prescribe the amount of security deposit for the access licence. See section 37(e) of the Sabah Biodiversity Enactment 2000), **Philippines** (The applicant shall post a rehabilitation/performance bond in the form of a surety bond in an amount equivalent to 25% of the project cost. See section 12.1 of the Philippines Guidelines for Bioprospecting 2005).

administrative arrangements include establishing routes, ascertaining the types of material collected and methods of storage. Fulfilling other preconditions, like securing the PIC of relevant stakeholders including ILCs and negotiating contracts, is also time consuming. Sometimes there is a final vetting process by the NCA. Often there is a public consultation process. These processes can significantly extend the time for making the decision. An applicant for research and/or commercial use of the genetic resource would desire clear (and early) deadlines especially for the access decision. Hence, timelines are a crucial indicator of the facilitation of the access process; and suggests how soon the genetic resources may be made available for research and/or use.

Ultimately, this will have a bearing on the ready availability of genetic resources for exchange and use at a pace that would allow for facilitated research and development. More importantly, farmers, breeders, pastoralists and fisher-folk would be clearly handicapped in carrying out their continuous use and exchange of GRFA if they have to comply with unspecified timelines to access such resources, unless of course they are exempted from making these applications; or the process is fast-tracked.

Several countries prescribe specific times for processing the application.[280] Some provide timelines for some stages of the application process only. However, most do not prescribe any time limit.[281] The length of time could however be inferred from the layers of the process and the number of authorities involved in dealing with the application.[282] Even in those countries where a single authority deals with the access application and issues the PIC, there is an obligation to negotiate the access agreement after the PIC is given.[283] Then again typically in most countries,[284] the PIC must be obtained from owners of private land as well as indigenous peoples, depending upon where the genetic resource is accessed.

Where the consent is from nomadic tribes, for example, time may be extended quite substantially.[285] Often a benefit-sharing agreement must be entered into with the stakeholder. This will be overseen, and in some cases, endorsed or vetted, by the state body authorized to give the permit for access. In some countries,[286] the NCA itself negotiates and concludes the agreement based on the PIC of the ILCs. The

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[280] **Guyana** (3 months before commencing the research project; and the application is processed within 1 month: This requirement does not appear in the Draft Regulations), **Bolivia** (the application process will take up minimum 40-70 days: This is the minimum estimation because the law does not provide for timeline at all stages. Only 3 stages are given attention. Article 22, 24 and 26 of the Bolivian Regulations on Access 1997), **India** (application is processed within 6 months from the date of its receipt, extension of time is not provided: Rule 14(3), Indian Biodiversity Rules 2004), **Vanuatu** (the Council must meet within 21 days after receiving an application from the Director to determine that application and the Decision must be communicated in writing within 14 days to applicant: Section 34(1),(3), Vanuatu Environment Act 2003), **Bhutan** (30 days for decision from receipt of application), **Kenya** (to make and communicate decision in writing to the applicant within 60 days of receipt of the application: Regulation 13, Kenyan ABS Regulations 2006), **Costa Rica** (30 natural days to resolve an application)**,**

[281] **Brazil, Uganda, Hawaii, Gambia, Pakistan, Sabah, ASEAN Framework Agreement and Nigeria**. The Bonn Guidelines neither provide for actual timeline or deadline nor require Parties to provide for it in their national laws. The Guidelines only encourage decisions on applications for access to be made within a reasonable period of time. The Guidelines advises users to seek PIC adequately in advance to facilitate access – Article 33. The internet seems to have reduced considerably the time for processing applications in **Brazil** – at least for licences to issue to collect biological material for scientific research and teaching purposes. Licences can be issued in 45 days with the simplest cases resolved in 7 days: Marina Ramalho, 'New System to Boost Biodiversity Access in Brazil', *Science and Development Network,* 12 March 2007, available at http://www.scidev.net/en/news/new-system-to-boost-biodiversity-access-in-brazil.html.

[282] In **Malawi**, for example, affiliating institutes or certifying institutions review the application before submission to the National Research Council. Upon approval by the National Research Council, the certifying institutions issue a certificate of approval to the applicant.

[283] **Ethiopia.**

[284] **Bhutan**, **Afghanistan, Guyana** (This is provided for in the Draft Regulations but not in the Guidelines), **Nigeria** clear exception: **Malawi**

[285] **Afghanistan.**

[286] **Ethiopia.**

PIC from the ILCs to the terms of the agreement is mandatory in almost all countries. The process is often intricate and elaborate to ensure that the consent is truly 'informed' (for example, it must be in language understood by the ILCs, or otherwise made known through an interpreter) and the communities have understood the implications of the grant of access as well as the terms upon which it is granted.[287] Some countries also provide for a withdrawal or restriction of the PIC given earlier by ILCs.[288] All these requirements, inspired by the need to protect the interest of ILCs, nevertheless add considerably to the time it takes to access the genetic resource**.** Case studies by others show that receiving PIC from all parties and formalizing this in agreements takes 1 – 2 years on average and sometimes longer.[289]

Some countries provide an elaborate and time consuming process to allow for public input for applications for access for a commercial purpose. But most countries do not provide timelines to manage the process. A few do. **Australia** is an example,[290] of a country that provides a time period for the completion of this public consultative process.[291]

Bangladesh makes available the completed application 'easily and readily accessible by any citizen' for at least 30 days.[292] **Bolivia** establishes a timeline for the NCA to publish a summary in a written and oral medium of communication of national circulation for public consultation; and for a technical evaluation of the application. **Bolivia** establishes a time period not for the entire approval process, but for some of the stages only.[293] Some prescribe that all applications must be processed within a reasonable time.[294]

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[287] **Guyana.**

[288] **Ethiopia.**

[289] Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors,* CBD, UNEP, 2008 at p. 25.

[290] Environment Protection and Biodiversity Conservation Regulations 2000, Division 8A.4, regulation 8A.16(3).

[291] There is a time established: for the Minister to inform the applicant that the application is required to be assessed by public notice, and, the applicant is to give the authority a summary of the likely environmental impacts; for the publication then on the internet of a notice inviting any person to comment on the likely environmental impacts of the proposed access; for inviting persons registered to give comments; for publishing on the internet any document relevant for public consideration of the proposed access and its environmental impact; and after the end of the period allowed by the invitation for comments, for giving the applicant a copy of any comments received by the Minister. This power to require an assessment of environmental impact by public notice only applies if the Minister believes, on reasonable grounds, that the proposed access to biological resources is likely to have more than negligible environmental impact.[291] Although the definition of biological resources is wide and goes beyond wild and natural resources, the discretionary powers vested in the Minister are circumscribed by the need to establish the potential for some significant adverse environmental impact. The power for an EIA is hence unlikely to extend to normal commercial activities in relation to genetic resources of domesticated species of plants and animals. **Philippines** established for bioprospecting purposes, a timeline of 15 working days after receipt of the completed required documentation, for the technical committees of the relevant Departments to make a final evaluation of the application.[291] It is then forwarded to the appropriate agencies with recommendation for approval or rejection.[291] As far as practicable, within one month from the submission of the recommendation, the agencies must give a decision approving or rejecting the application.[291] For non-commercial scientific research, a Memorandum of Agreement must be signed and the permit issued, as far as practicable, within one month after submission and completion of all requirements.[291]

[292] Article 13(10) of the Bangladesh Biodiversity Act 1998.

[293] Once the applicant is notified of the approval they must within the following 5 days proceed to negotiate the Access Contract. The minimum estimation for the whole process is about 40 – 70 days: This is based on a calculation of the time periods in Articles 22, 24 and 26 of Bolivia's Regulation of Decision 391, 1997. The public consultation applies to all applications for access to genetic resources. There seems to be no power to exempt any such resource from this process.: Regulations on Access 1997, Article 22.

[294] **South Africa:** Regulation 7(1), South African ABS Regulations 2008. The applicant must be notified of the decision in writing within 15 working days of the decision: Regulation 7(3)(a) and (c), South African ABS Regulations 2008. If the application is approved, the authority must issue the permit within 15 working days after making the decision: Regulation 7(3)(b), South African ABS Regulations 2008. Permit holders must lodge a copy of any relevant benefit-sharing agreement with the Director-General of the Department of Environmental Affairs and Tourism within a month of the agreement being concluded: Regulation 17(5), South African ABS Regulations 2008.

Where there are no timelines provided by the laws for the processing of applications for access, which is the case with most ABS laws, the free use and exchange of GRFA could be unduly hampered. Even where full or partial timelines are prescribed, this time can be extended. The actual duration of the time for processing the application is beyond the scope of this study. However, given that approval has to be sought from several authorities, the capacity of these authorities and the several other requirements that require time to fulfil, it is predictable that the time period will be significant. Furthermore, ABS laws are entirely new for most countries, and this will make it even more difficult to achieve rapid approvals. As countries try to cope with the implementation of new laws, new or additional information may be predictably sought, leading to delays in approving an application for access.

At least in one sector of food and agriculture, this lengthy approval processes may present severe problems. This is the area of biocontrols or biosecurity.[295] It is often of critical importance to be able to access and introduce bio-control organisms as soon as a pest emerges and it can be determined that biocontrol organisms are appropriate responses.

5. Appeal procedures

Most countries provide for a process by which appeals can be made when access applications are rejected or when conditions for access are to be imposed. The body to which such appeals are to be made, differs from country to country, and may include appeals to the Minister,[296] a tribunal,[297] an appropriate administrative channel,[298] the State Government,[299] the Supreme Court,[300] and to a responsible Management Council[301].

No time is prescribed for the appeal process. This is usually dealt with by implementing regulations. Appeals may serve a useful access to justice issue. Nonetheless the process adds to the time for allowing access and could unduly impede the exchange of GRFA.

6. PIC from ILCS and other stakeholders

Earlier we discussed the need to seek the PIC of the State authorities to obtain access to genetic resources. As noted, most laws require that the PIC of other stakeholders should also be obtained as a condition for the approval for access.[302] The Bonn Guidelines endorse this approach.[303] These multifarious stakeholders

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[295] Defined as the protection of the economy, environment and human health from negative impacts associated with pests, diseases and weeds: Australian Government, September 2005, cited in John Lovett, *Biosecurity, Biodiversity and Plant Genetic Resources,* Talk at MOSTI, Malaysia, May 2009, power point presentation.

[296] **South Africa** (An applicant or a permit holder may lodge an appeal with the Minister against any decision to refuse a permit, to impose permit conditions that are in addition to the mandatory conditions required by the Regulations, or to cancel a permit. See section 94 of the South African Biodiversity Act 2004 and Regulations 14 and 15 of the ABS Regulations 2008).

[297] **Guyana** (Any person who is aggrieved by a decision of the EPA may at any time within 14 days appeal by notice in writing to the Environment Appeals Tribunal established under section 51 of the Guyana Environmental Act 1996. See Regulation 24 of the Guyana Draft Regulations 2001), **Kenya** (A person aggrieved by the refusal of the National Environment Management Authority to grant a licence may appeal to the National Environment Tribunal established under section 123 of the Kenyan Environmental Act 1999).

[298] **Pakistan** (Article 9 of the Pakistan Draft Law on Access 2004).

[299] **Sabah** (Section 22 of the Sabah Biodiversity Enactment 2000).

[300] **Vanuatu** (Section 43 of the Vanuatu Environmental Act 2003).

[301] **Brazil, Costa Rica, Bolivia** (Applicants may appeal against any denied petitions for access and the appeal will be heard by the Ministry of Sustainable Development and the Environment. See Article 5, Bolivian Regulations on Access 1997).

[302] **Bolivia, Brazil, Costa Rica, Hawaii, Pakistan, Uganda, Vanuatu** (By inference, as 'PIC' is not mentioned in the ABS law of Vanuatu. However, the resource user is required to conclude a contract with the relevant custom landowners or owners of TK concerning rights of access, rights of acquisition of any biological resource or TK, and benefit-sharing. See section 34, Vanuatu

were listed n the earlier discussion.[304] Some of the PIC related requirements were also discussed. This section addresses other provisions relating to PIC from stakeholders other than the state.

Some countries and regional laws require PIC for access without reference to the purpose for which such access is sought.[305] Other countries and regional laws specify the activities for which PIC is required, including bioprospecting,[306] research,[307] bioprospecting and research,[308] bioprospecting, research and conservation,[309] access and shipment,[310] bioprospecting, export for bioprospecting and export for research other than bioprospecting,[311] exportation and research.[312]

Only two countries specify information for inclusion in the PIC. The information is as follows:

- Meaning and scope of access;[313]
- Term of protection of the related knowledge;[314]
- Practical, economic and logistic aspects of the access;[315]

Environmental Act 2002), **Australia** and the Australian states of the **Northern Territory** and **Queensland** ('PIC' is not defined in the Act but the Act provides that the competent authority granting PIC is the EPA chief executive). **Bulgaria (**PIC is not specified in the Act. However, the Act provides that the state shall own the genetic resources of the natural flora and fauna of the republic of Bulgaria. here is a good example, the focus in on natural flora and fauna, not domesticated. this is a key point. if all ABS laws focussed on wild or natural genetic resources, impacts on GRFA would be minimal. This necessarily implies that the PIC of the state should be obtained before access can be granted), **Bangladesh, Afghanistan, Bhutan, Ethiopia, Malawi, Bulgaria, Nigeria, Kenya, Philippines** and **South Africa**. The same requirement is imposed by several regional laws: the **ASEAN Framework Agreement** and the **African Model Law**. This is in accordance with Bonn Guidelines. The Guidelines recognize the importance of the relevant stakeholders, including ILCs, to be consulted, when determining access and their consent should be obtained. – Article 18 and 26(d).

[303] Article 26(d).

[304] See Chapter IV, paragraph 2(c) subheading 'Parties to MATs and PIC'.

[305] Bonn Guidelines do not differentiate between activities for which PIC is required. **Bolivia** (Access and development of activities, intangible components), **Costa Rica** (Access to components of biodiversity and associated knowledge, **Pakistan** (Access to biological resources, knowledge, innovations and practices), **Uganda** (Access to genetic resources, including their derivative products and intangible components), **Vanuatu** (Acquisition of biological resources and TK), **Australia** (Access to genetic resources for commercial and non-commercial purpose), the Australian state of **Queensland** (Access to collecting native biological materials by bio-discovery entities), **Bulgaria** (Access to genetic resources of the natural flora and fauna of the Republic of Bulgaria), **Afghanistan** (Access to genetic resources), **Kenya** (Access to genetic resources), **Nigeria** (Access to genetic or biological material found in National Parks, and genetic material or associated indigenous knowledge owned or in the possession or custody of a Nigerian citizen, group or association), and the **ASEAN Framework Agreement** (Access to biological and genetic resources and associated TK).

[306] **Hawaii**, the **Northern Territory** of Australia (Access to genetic resources for bioprospecting), **Guyana** (Access to genetic and biological resources for bioprospecting for any or a combination of the following purposes: academic, commercial, industrial or conservation. See the Guyana Draft Regulations 2001).

[307] **Malawi** (Access to genetic resources for research purpose).

[308] **Bangladesh** (Access to biological and genetic resources for research and commercial use), **Philippines** (Access to resources for bioprospecting purposes and research purposes), the **African Model Law** (Access to biological resources and to the knowledge and technologies of local communities for research or commercial purposes).

[309] **Bhutan** (Access to genetic and biochemical resources for the purpose of conservation, research, bio-prospecting or commercial use).

[310] **Brazil** (Access and shipment of samples of genetic heritage and associated TK).

[311] **South Africa.**

[312] **Ethiopia** (Access to genetic resources or community knowledge for exportation out of Ethiopia or for research purpose).

[313] **Costa Rica**.

[314] **Costa Rica**.

[315] **Costa Rica**.

- Owner of the resources;[316]
- Details of the resources;[317]
- Duration of access;[318] and
- Details of accessory agreements.[319]

The information required by these countries is cumulative.

Most countries require PIC to be obtained before access is granted.[320] Some countries specify that PIC is to be obtained prior to the commencement of the activity for which access is sought.[321] In some cases, PIC may be required before a benefit-sharing agreement is entered into,[322] or before the application for access is made.[323]

Some countries exempt research institutions or universities from the PIC requirement.[324] In addition, some countries provides for an exemption in instances of public interest as defined by relevant authority.[325] Some countries make it an offence to access genetic resources without the required PIC.[326]

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[316] **Uganda.**

[317] **Uganda**.

[318] **Uganda**.

[319] **Uganda**.

[320] **Bolivia** (The Annex and Accessory Contract, which contain the PIC, are to be entered into before the Access Contract is concluded), **Vanuatu, Australia**, the Australian state of the **Northern Territory**, **Afghanistan**, **Bangladesh**, **Bhutan**, **Malawi**, **Ethiopia**, **Uganda** (Before the granting of the access permit and after obtaining accessory agreements), **Philippines**, **South Africa**, and the **African Model Law**.

[321] **Hawaii** (PIC to be given prior to the commencement of a prospective bioprospecting venture), **ASEAN Framework Agreement** (PIC to be obtained after fully disclosing the intent and scope of the access to biological and genetic resources and before any such access activity is undertaken).

[322] **Queensland.**

[323] **Guyana (**Under the draft Regulations, where the access sought is in respect of private lands, the applicant shall submit a copy of the agreement from the owner or occupier of such lands together with the application).

[324] **Brazil** (A Brazilian research institution or university which has obtained special authorization for access and shipment of genetic heritage and associated TK is exempted from the PIC requirement), **Ethiopia** (The terms and conditions of access procedure or requirement of the Proclamation may not be strictly adhered to for access applications by research institutions).

[325] **Brazil** provides for an exemption in instances of public interest as defined by the Management Council. In such a case, the law contains safeguards to ensure that benefits arising from economic use of the product or process developed from samples of genetic heritage components and associated TK must be shared among stakeholders and the Federal Government. In addition, the indigenous community, local community or landowners must be given prior notice that entrance will be made into the area concerned for access to samples of genetic heritage components.

[326] **Uganda, Nigeria.**

V. BENEFIT-SHARING: MUTUALLY AGREED TERMS (MATS)

This section deals with benefit-sharing. Generally, benefit-sharing is based upon MATs. The terms are negotiated by the country, organization of person seeking access and the provider country (through its designated authority).[327] Other parties may also be involved in the negotiation in addition to, or in lieu of, the NCA – such as the land owner or ILCs. There may be other terms in addition to benefit-sharing which may also be mutually agreed and/or required by the resource provider. These are dealt with in the next section.

Essentially, MATs for benefit-sharing reflect a commercial arrangement between the relevant parties and an agreement will be entered into. All ABS laws invariably make the incorporation of benefit-sharing terms a crucial precondition to securing access to genetic resources or associated TK. Some laws do not stipulate any specific benefit-sharing terms.[328] Several others merely provide an indicative list of benefits which may be shared.[329] A number of laws state the benefit-sharing terms which must be included,[330] but leave room for either the parties to negotiate further terms, or for the state authority to impose additional terms.[331]

Several laws, in addition to setting out a list of minimum benefit-sharing terms, also list optional benefit-sharing terms which the parties may decide to incorporate into their agreement.[332] Some others set out a list of benefits, one or more of which must be shared but it is not mandatory to include all of them.[333]

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[327] Article 15.7, CBD. The CBD requires parties to take measures to ensure benefit-sharing. These must be on MATs. Some countries require MATs to be negotiated. **Bolivia, Brazil, Costa Rica, India, Pakistan, Uganda, Vanuatu, Queensland** (in the form of benefit-sharing provisions: section 33, Queensland Biodiscovery Act 2004)**, Northern Territory, Bangladesh, Afghanistan,** and **Malawi**.

[328] **Hawaii**, and **Sabah**.

[329] **Brazil, Vanuatu, South Africa,** and the **ASEAN Framework Agreement, India** and **Kenya** (adopts the entire list in the Bonn Guidelines. The holder of an access permit is required to facilitate the active involvement of Kenyan citizens and institutions in the execution of the activities for which the permit is granted, including the enjoyment of both monetary and non-monetary benefits).

[330] **Bolivia**, **Guyana**, and **Nigeria**. This is not the same as the minimum clauses that most countries prescribe that go beyond benefit-sharing provisions and which are included in the MATs: **Bolivia** (The law provides in detail for a minimum number of mandatory clauses), **Brazil** (The Provisional Act provides a list of mandatory clauses), **Pakistan** (A list of requirements and minimum conditions is set out in the law), **Uganda** (Mandatory (minimum clauses) and model clauses are provided for MTA), **Bulgaria** ('Mutually advantageous terms' are specified in the Act), **Bhutan** (Minimum terms are provided in the form of benefit-sharing provisions in the Act), **Afghanistan**, **Bangladesh**, **Ethiopia**, the **African Model Law**, **Australia**, **Queensland**, the **Northern Territory**, **Guyana**, **Nigeria**, **South Africa**, and the **Philippines**. **Costa Rica** prescribes a number of minimum clauses and also sets out a list of optional clauses.

[331] **Ethiopia** (Provides for minimum content of access agreements to be imposed by the Institute of Biodiversity Conservation; however, the kind and amount of benefit to be shared shall be determined on a case by case basis in each specific access agreement), **Bhutan** (Sets out several conditions for benefit-sharing, one or more of which are required to be included in the MTA or Contract Agreement to be signed between the Competent Authority and the applicant), **Guyana** (Under the Guyana Draft Regulations 2001, every Research Agreement is to be in the prescribed form and to contain minimum terms. The Guidelines for Biodiversity Research set out terms which every Research Agreement must contain, but does not indicate whether these terms are exhaustive or whether other terms can be negotiated or imposed), **Nigeria** (Resource users are required to give certain undertakings, including an undertaking to share benefits derived from the resources with the Government and people of Nigeria; however, the exact terms of such benefit-sharing are not prescribed), **Philippines** (Bioprospecting Undertaking to contain standard terms and conditions as listed in Annex I, in addition to negotiated terms of benefit-sharing), **South Africa** (Benefit-sharing agreements must be in the prescribed format and contain the information specified in the South African Biodiversity Act 2004, in addition to any other matters that may be prescribed. Parties are free to determine benefit-sharing terms, although the Bio-prospecting, South African ABS Regulations 2008 provides lists of possible benefits that may be shared).

[332] **Pakistan**, **Uganda**, and the **Philippines**.

[333] **India**.

Some do not prescribe any specific minimum terms but make general provisions through guidelines.[334] Some list the monetary and non-monetary benefits which may be shared but does not indicate whether these benefits are mandatory.[335]

The benefits are both monetary and non-monetary. Many ABS laws provide for the benefits to be shared in a 'fair and equitable' way.[336] For this reason, state authorities retain the power in some ABS laws to vet the agreement to ensure that the benefits meet this criterion. This sometimes results, in effect, in the provider country stipulating the inclusion of certain terms to ensure an evenly balanced agreement. Practically, the State imposes some terms that it considers of importance. This is especially useful where MATs are negotiated with a inexperienced party, such as a local community. In such a situation MATs are not truly negotiated and agreed to by the parties themselves. [337] The State authority vets the agreement and may, or may not, be a party to the negotiations and/or agreement. Of course, if these terms are not agreed to by the applicant, no agreement results.

Most countries require MATs to be negotiated before access is granted.[338] However, in several countries, MATs need to be negotiated only after the access application has been approved.[339] Some countries specify that MATs are to be negotiated after PIC is obtained but before access is granted.[340] Occasionally, MATs may need to be negotiated before PIC is granted.[341] Some variations exist.[342]

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[334] **Malawi** does not prescribe any specific minimum terms, but its guidelines list several aims to be achieved from research activities carried out in Malawi; it may be implied that any terms to be mutually agreed between the parties must be consistent with the objectives of the Guidelines.

[335] **Kenya.**

[336] **India**'s law, for example, states that its NBA shall ensure that the terms and conditions subject to which approval is granted secures *equitable* sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with MATs and conditions between the person applying for such approval, local bodies concerned and the benefit claimers: section 21(1), The Biological Diversity Act, 2002. This is also stated in Article 15.7, CBD. See also Article 24, Brazil's Provisional Law.

[337] **African Model Law** (An agreement between the NCA and the applicant which contains commitments undertaken or to be undertaken by the collector; hence, these terms are not mutually agreed but are conditions imposed upon the collector prior to granting of access by the NCA), **Bulgaria** (The terms and procedure for provision of access to genetic resources shall be established by a regulation adopted by the Council of Ministers), **South Africa** (In material transfer agreements and must be in the prescribed format and contain the information specified in the South African Biodiversity Act 2004).

[338] **India**, **Pakistan**, **Afghanistan**, **Bhutan**, **Bulgaria**, **Malawi**, **Australia**, **Nigeria** (Consent to prospect for genetic resources shall not be granted unless the applicant undertakes, *inter alia*, to share the benefits derived therefrom with the Government and people of Nigeria), **Guyana**, **South Africa** and the **Philippines**.

[339] **Bangladesh**.

[340] **Ethiopia**, **African Model Law**, and the **Northern Territory**.

[341] **Uganda** (Accessory agreements must be entered into with relevant stakeholders before PIC is granted by a lead agency, local community or owner. All these must be done before the application for an access permit is made. This is then followed by a material transfer agreement with the lead agency), **Nigeria** (PIC may be given subject to benefit-sharing arrangements).

[342] In **Bolivia** before the applicant signs an access contract with the national authority, it must enter into an accessory contract with those involved in providing access – the landowner, the entity responsible for the *ex situ* conservation or the owner of the biological resource containing the genetic information. If TK, innovation and practices, are involved, the access contract must include an annex regulating the equitable sharing of benefits between the provider of TK and the user. The accessory contract is entered into after the annex but before the access contract is signed. The sequence in which the contracts are entered into then is: annex (if TK involved), accessory contract, and the access contract. These contracts cumulatively represent the MATs. This provision is in accord with **Andean Decision 391**. In **Queensland**, the relevant biodiscovery plan[342] must have been approved before a benefit-sharing agreement can be entered into.

It is noted that generally there seems to be a paucity of laws and guidelines that provide for phased agreements. By this, for example, a permit or agreement authorises access but the benefit-sharing agreement is concluded later when a product is close to commercialisation.[343]

In most countries, MATs take the form of a contract or agreement.[344] In some countries, MATs are set-out in the access permit.[345] Whatever the form, most countries do not prescribe a standard/model format for MATs,[346] whereas a few countries do.[347]

Most countries require MATs to be vetted,[348] although some regional and national laws eschew such vetting requirements.[349] The party responsible for vetting MATs may include: the NCA or other relevant agency;[350] the Minister;[351] or a research/scientific institute.[352]

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[343] **Brazil** provides an example of such an arrangement. Its law requires the applicant to notify the authority who granted the access when a potential economic use is identified: '… when probability of commercial use is apparent': Article 16(5) of the Brazilian Provisional Act 2001. Then a Contract for Use of Genetic Heritage is formalized. This could give parties to the arrangement a clearer profile of the potential financial benefits and result in a benefit-sharing agreement that is fair and equitable. Some note that this could weaken the power of the applicant once a commercial use is found: See earlier discussion at Chapter III 2(c) Exemptions for research activities. Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors,* CBD, UNEP, 2008 at p. 29. **Costa Rica** requires a party to meet the requirements of bioprospection the moment the basic research begins to anticipate commercial or profitable purposes. This seems to suggest a further agreement: Article 7, General Rules for Access to the Genetic and Biochemical Elements and Resources of the Biodiversity, 2003.

[344] **Bolivia** (Access Contract, Accessory Contract and/or Annex to Access Contract), **Brazil** (Contract for Use of Genetic Heritage and Benefit-Sharing), **Costa Rica** (Model contract prepared by the Technical Office), **India**, **Pakistan**, **Uganda** (Accessory agreement, a facilitating agreement relating to PIC and material transfer agreement, agreement between the Government and the collector, setting out the terms under which genetic resources can be transferred from one party to another), **Vanuatu**, **Bangladesh**, **Ethiopia** (Genetic resources access agreement), **Malawi** (Research and material transfer agreement), **Australia**, **Queensland**, the **Northern Territory**, **Guyana** (Research Agreement), the **Philippines** (Bioprospecting Undertaking to contain negotiated benefit-sharing terms in addition to standard terms and conditions), **South Africa**, and the **African Model Law**.

[345] **Afghanistan**.

[346] **Bolivia**, **Brazil** (The Management Council is responsible for establishing guidelines for drafting the Contract), **Costa Rica**, **India**, **Pakistan, Vanuatu, Guyana**, **Nigeria**, **Kenya**, **Bhutan**, **Afghanistan** (The access permit reflects the MATs), **Ethiopia** (The Institute has the duty to prepare the model access agreement), the **African Model Law**, **Bangladesh**, **Queensland** (Parties may amend the agreement at any time), and the **Northern Territory** (The Minister may publish in the *Gazette* a model benefit-sharing agreement as a guide).

[347] **Uganda** (Accessory contract, the form is set out in 3rd Schedule; standard clauses for MTA are set out in 4th Schedule of the Uganda ABS Regulations 2005), **Malawi** (Research and material transfer agreement), **Australia** (Access and benefit-sharing agreement), the **Philippines** (Standard terms and conditions for Bioprospecting Undertaking set out in Annex I to the Philippines Guidelines for Bioprospecting 2005; SMTA set out in Annex II thereto), and **South Africa** (Format for MTA set out in Annexure 7 of the South African ABS Regulations 2008; format for Benefit-Sharing Agreement set out in Annexure 8 thereto).Bonn Guidelines recommend developing standard material transfer agreements and benefit-sharing arrangements for similar resources and similar uses. The countries surveyed with standard/model agreements did not differentiate between different resources and different uses.

[348] **Bolivia** (Once the Access Contract has been subscribed among the petitioner and the Under-Secretary's Office of Natural Resources, the National Secretary of Natural Resources and the Environment shall issue a Secretarial Resolution to confirm the Access Contract. See Article 27 of Bolivian Regulations on Access 1997), **Brazil, Costa Rica, India, Uganda, Malawi** (The Genetic Resources and Biotechnology Committee shall be the sole authority to approve research and MTA on genetic resources), **Australia, Queensland,** the **Northern Territory**, the **Philippines**, and **South Africa** (Benefit-sharing and material transfer agreements do not take effect unless approved by the Minister. See sections 83(2) and 84(2) of the South African Biodiversity Act 2004).

[349] **Vanuatu**, **Pakistan**, **Bangladesh** (However, the National Biodiversity Authority reserves the right to unilaterally withdraw its consent and terminate the agreement), **Guyana**, **Nigeria**, **Kenya**, and the **African Model Law** (Although the National Inter-sectoral Coordination Body is to ensure that minimum terms in the agreement are complied with).

[350] **Bolivia** (the National Secretary of National Resources and the Environment), **Brazil** (the Council), **Costa Rica** (the Technical Office), **India** (the NBA), **Afghanistan** (the National Environment Protection Agency), **Bhutan**, **Malawi** (the Genetic Resources

There is a range of monetary benefits to be shared.[353] These include:

- Sharing of profits;[354]
- Flat fee and/or fee per sample;[355]
- License fees;[356]
- Upfront payments;[357]
- Royalties;[358]
- Milestone payments;[359]
- Concessions;[360]
- Special rates or special provisions in relation to products derived from the access;[361]
- Research funding;[362]
- Payment of salaries;[363]
- Venture capital funding;[364]
- Recognition and/or co-ownership in IPRs;[365]

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and Biotechnology Committee), the **Northern Territory** (CEO of the Agency), the **Philippines** (technical committees of the implementing agencies).

[351] **Queensland** (DSDI Minister), **Australia**, **South Africa.**

[352] **Ethiopia** (the Institute of Biodiversity Conservation).

[353] Bonn Guidelines recommends that the time period for monetary benefits should be considered namely near-term, medium term and long term benefits – Article 47. This approach is adopted by **India** - Rule 20(6), India Biodiversity Rules. The range of benefits stated in the national laws surveyed is similar to the indicative list in Appendix II of the Bonn Guidelines.

[354] **Bangladesh** (at least 50% of the profit generated from commercial activities will have to be shared with the communities), **Philippines** (payments from product sales), **Guyana** (the Research Agreement must include a provision for the payment of an agreed part of any financial gain, including royalties, derived from the research and/or the development of any biological or genetic material taken from Guyana to the Guyana Government, local or indigenous cultural community, individual person or designated beneficiary, in the event that a commercial application for the material concerned is discovered), **Pakistan** (State to ensure that a minimum of 10% benefit obtained from any commercial use of biological resources are to be paid to the local community concerned), **Costa Rica** (possible commercial benefits at short, mid and long term of any product or sub-product derived from the acquired material), **Brazil.**

[355] **Bhutan** (flat fee), **Ethiopia** (license fee), **South Africa** (fees), **Philippines** (bioprospecting fee), **Kenya** (access fee or fee per sample collected or acquired,), **Vanuatu** (fees), **Uganda** (access fees).

[356] **Kenya, Uganda**.

[357] **Bhutan, Ethiopia, South Africa, Philippines, Kenya**.

[358]**Bhutan, Ethiopia, South Africa, Philippines, Kenya, Vanuatu, Uganda, Costa Rica** (obligation to pay up to 50% of the royalties obtained to the Conservation Areas National System, the indigenous representatives, the landowners or owners or persons responsible for the materials kept in *ex situ* conditions), **Brazil, Bolivia, Pakistan** (provision for payment of royalties or a fixed sum to the national government or local communities in case commercial use is derived from the biological resources taken).

[359] **Bhutan, Ethiopia, South Africa, Kenya**.

[360] **Vanuatu**.

[361] **Bhutan** (concessionary rates or free supply of commercial products derived from the resources provided), **Brazil** (licensing, without cost, of products and processes), **Bolivia** (franchises granted to the country by marketers or processors of the genetic resources accessed).

[362] **Ethiopia, South Africa** (grants for development and environmental education projects), **Kenya, Uganda**.

[363] **Kenya, Uganda**.

[364] **India** (setting up of venture capital fund for aiding the cause of benefit claimers).

- Fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;[366]
- Other payments;[367]

The non-monetary benefits[368] identified in the ABS laws include:

- Sharing of research results and relevant information;[369]
- Access to research data and collections;[370]
- Transfer of technology;[371]
- Participation of local institutions and/or personnel;[372]

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[365] **Bhutan** (recognition as a partner in intellectual property ownership of products derived from the supplied material), **Ethiopia** (joint ownership of IP), **South Africa** (co-ownership of any IPRs), **Kenya** (joint ownership of IPRs), **Uganda** (joint ownership of patents and other relevant forms of IPRs), **India** (grant of joint ownership of IPRs to the NBA or benefit claimers), **Brazil, Bolivia** (ownership of IPRs).

[366] **Kenya, Uganda.**

[367] **Costa Rica**, for example, imposes a requirement on the applicant to provide up to 10% of the research budget, and up to 50% of the royalties for maintaining National Conservation Areas, or to the indigenous territory or the private owner providing access to the genetic resources: Section 76, Costa Rican Biodiversity Law 1998. This generates some complications since there will not always be a research budget or controversies may arise in relation to the scope of the requirement: Jorge Carbrera-Medaglia, *'Legal Framework and Public Policy',* Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the CBD, IUCN Environmental Policy and Law paper No. 54, 2004, p 114. As a result, agreements have to oust this provision by inserting a clause clarifying that in the event the budget cannot be used as a basis for calculations, other formula for the distribution of benefits should be designed: ibid. at p. 121 citing the agreement between Ministry of Environment and Energy and INBIO.

[368] The Appendix II of the Bonn Guidelines provides an indicative list of the non-monetary benefits. Many national laws seem to have selected many of these.

[369] **Bangladesh, Bhutan, South Africa** (research results and copies of papers; ongoing communication of bioprospecting objectives, methods and findings translated into local languages; posters, manuals, pamphlets and other documents translated into local languages; access to research data; copies of photographs and slides), **Kenya, Bolivia** (obligation to inform the Competent National Authority about the results of the research carried out)).

[370] **South Africa** (access to international collections by South Africans), **Philippines** (Filipino citizens and Philippine governmental entities to be allowed complete access to specimens deposited at an internationally recognized *ex situ* depository or genebank), **Kenya** (admittance to *ex situ* facilities of genetic resources and databases by participating institutions), **Uganda** (access to scientific information such as biological inventories and taxonomic studies), **Brazil** (exchange of information).

[371] Bonn Guidelines emphasize fair and equitable sharing of benefits to include transfer of technology – Article 16(b)(ix). This appears in the national ABS laws of: **Afghanistan, Bangladesh, Bhutan, South Africa, Philippines, Kenya** (transfer to Kenya of genetic resources of knowledge and technology under fair and most favourable terms), **ASEAN Framework Agreement, Uganda** (transfer of knowledge and technology under favourable terms), **India**, **Costa Rica** (transference of technology or generation of information derived), **Brazil, Bolivia** (strengthening of mechanisms for the transfer of know-how and technology; transfer of technologies, methods, equipment, materials, knowledge and others used in the investigation and/or experimentation).

[372] Bonn Guidelines emphasize that users should endeavour to carry out the use of genetic resources with the participation of the providing country – Article 16(b)(vii). This appears in the national ABS laws of: **Afghanistan** (participation of Afghan nationals and national institutions in any research carried out with the genetic resources), **Bhutan** (joint research activities; identification of national institutions which will participate in the research as well as an indication of any plans for cooperation with national institutions, scholars, scientists, students, farmers and farmer groups), **Ethiopia** (participation of Ethiopian nationals from the Institute or relevant institutions based on the genetic resource or community knowledge accessed), **South Africa** (joint research activities; participation of South Africans in research; inclusion of local collaborators, assistants, guides and informants), **Philippines** (no Bioprospecting Undertaking shall be executed with a foreign resource user unless a local collaborator has been engaged; all bioprospecting researches by any foreign entity or individual to be conducted in collaboration with Philippine scientists), **Kenya** (collaboration, co-operation and contribution in scientific research and development programmes; participation in product development), **Nigeria** (research collaboration with Nigerian scientists), **Guyana** (the research team to collaborate with local institutions or individuals; the research team to included local counterparts), **Uganda** (participation by Ugandan citizens and institutions in scientific research and other activities involving access to genetic resources), **Brazil** (establishment of joint technologically based undertaking), **Bolivia** (participation of a National Support Institution in any investigation and/or experimentation carried out with the genetic material accessed and involvement of local citizens or institutions).

- Recognition and/or co-ownership in IPRs;[373]
- Participation of the access provider in the economic, social and environmental benefits accruing from the access;[374]
- Training and capacity building;[375]
- Acknowledgement of the origin of the genetic resource;[376]
- Donation of equipment to national institutions;[377]
- Employment opportunity;[378]
- Access to products and technologies developed from the use of genetic resources or knowledge accessed;[379]
- Support for conservation;[380]
- Species inventories, including deposit of samples;[381]

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[373] **Bhutan** (recognition as a partner in intellectual property ownership of products derived from the supplied material), **Ethiopia** (joint ownership of IP), **South Africa** (co-ownership of any IPRs), **Kenya** (joint ownership of IPRs), **Uganda** (joint ownership of patents and other relevant forms of IPRs), **India** (grant of joint ownership of IPRs to the NBA or benefit claimers), **Brazil, Bolivia** (ownership of IPRs).

[374] **Bangladesh** (participation of Bangladesh in the economic, social and environmental benefits accruing from the products and processes obtained through the use of biological and genetic resources found in the national territory), **Queensland** (described as 'benefits of bio-discovery'; includes any economic, environmental or social benefits for the state), **Costa Rica** (equitable distribution of environmental, economic, social, scientific or spiritual benefits), **Bolivia** (participation of the Government and peasant or indigenous communities in economic, technological benefits or others of any nature).

[375] **Bhutan, Ethiopia** (training, both at institutional and local communities levels, to enhance local skills in genetic conservation, evaluation, development, propagation and use; provision of equipment, infrastructure and technology support), **South Africa** (student training and support; scientific capacity development; information, equipment and infrastructure; community development projects; environmental education; training of local people in relevant scientific, legal and management issues; equipment and infrastructure support), **Philippines** (equipment for biodiversity inventory and monitoring; supplies and equipment for resource conservation activities, formal training including educational facilities; infrastructure; health care; other capacity building and support for *in situ* conservation and development activities), **Kenya** (strengthening capacities for technology transfer in Kenya; institutional capacity building; human and material resources to strengthen the capacities for the administration and enforcement of access regulations; training related to genetic resources with the full participation of Kenya), **ASEAN Framework Agreement, Uganda** (collaboration in education and training related to genetic resources; contribution to the development of the local community), **India** (association of Indian scientists, benefit claimers and local people with research and development), **Brazil** (capacity building of human resources; consolidation of scientific research and technological development infrastructure), **Bolivia** (strengthening and development of institutional capacity; strengthening and development of the capacities of the native, Afro-American and local communities; development of the technical and scientific capabilities of national institutions).

[376] **Bhutan** (acknowledgment in publications resulting from the research activities), **South Africa** (acknowledgment of parties giving access to resources).

[377] **Bhutan**.

[378] **Ethiopia**.

[379] **Ethiopia, Philippines** (resource user to make available to the Philippine government and resource providers all discoveries of commercial products made or derived from Philippine resources as may be agreed upon in the Bioprospecting Undertaking; resource user to make available to the Philippine government the use of technology developed from the conduct of research on Philippine endemic species, commercially and locally, without paying royalty to the resource user).

[380] **South Africa, Bolivia** (support for research of the genetic resource that contributes to the conservation and sustainable use of the biological diversity); **Brazil, India**. This is the ultimate goal for distribution of benefits under the Bonn Guidelines – Article 48.

[381] Examples: **Bangladesh** (deposit of subsamples from all specimens collected with a duly designated governmental entity), **South Africa, Brazil, India, Uganda, Pakistan** (deposit of duplicates of all specimens collected with a duly designated government institution).

- Recognition and promotion of TK or use.[382]
- Co-authorship of publications.[383]

Benefits relating to food security:[384]

- Location of production, research and development units in such areas as will facilitate better living standards to the benefit claimers.[385]

It is noted that at least one country mandated the inclusion of benefits relating to food security in a material transfer agreement or accessory agreement.[386] This linkage appears to be crucial for this country because high inputs, required by modern agriculture, has made some exotic crops costly for the majority of farmers to produce and significantly reduced food security in the country.[387] There are indigenous plants well adapted to the environment and that require low inputs. However, there is limited research to determine their potential contribution to human and livestock needs. Although there seems to be no elaboration of what specific benefits are to be included in the MTA, perhaps one such benefit could well be the much needed financial, technological and capacity assistance for research to determine and/or realise the potential of these plants to enhance food supply. Such benefits could also include the promotion of specific projects that would overcome specific problems of vulnerability of crops (example sweet potato and cassava) that threaten the critical aspects of food security.[388] The problems in this country in Africa are *'in many ways typical of those in other parts of the continent'.*[389] Some countries also explicitly refer to the criterion of food security in evaluating the access application whilst others subsume this in provisions relating to taking into account the public interest in making a decision for an application for access.[390]

It has been suggested that for ABS in relation to both microbial biodiversity and PGRFA, non-financial benefits may be more valuable to developing countries than financial benefits.[391] It is said that these benefits can be shared in the short-, medium- and long-term. They will accrue to the collaborators over the entire duration of the collaboration and enhance professional development for individuals; and capacity building and technology transfer at the country, regional and institutional levels will enable the collaborator to perform more value-added work. As a result, the collaborator may be able to generate additional revenues and access more upside potential by contributing more to the development of products resulting from the access agreements.[392]

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[382] **South Africa**.

[383] **South Africa**.

[384] **Uganda**.

[385] **India**.

[386] **Uganda**, ABS Regulations 2005, section 20(2)(h).

[387] UNU-IAS, *Access to Genetic Resources in Africa: Analysing ABS Policy Development in Four African Countries*, UNEP, 2008, at p. 44.

[388] CIP Annual Report '96(http://www.cipotato.org/publications/annual_reports/1996/uganda.htm).

[389] Ibid. Quoting CIP's sub-Saharan Africa regional office head, Peter Ewell.

[390] See later under Chapter IV.7. a under heading Approval/Denial of Access (Grounds for Denial of Access,.

[391] Charles Costanza et al, Deal Making in Bioprospecting, in *Intellectual Property Management in Health and Agricultural Innovation,* A Handbook of Best Practices (Eds. A Krattinger, RT Mahoney, L.Nielsen et al) MIHR: Oxford UK and PIPRA: Davis, US (online at www.ipHandbook.org), Chapter 16.4, p. 1495 at 1502.

[392] See preceding footnote.

A number of countries provide for the sharing of benefits of any IPRs[393] arising out of the utilization of the genetic resources accessed. Such benefits could include a benefit-sharing fee, royalty or sharing of financial benefits.[394] Some provide for joint ownership of IPRs.[395] In some countries the particular benefits that are to arise from the IPRs are not specified.[396] The Model Access and Benefit-sharing Agreement in **Australia**[397] clearly states that as between the access provider and access party, IPRs arising from research and development activity is vested or will vest in the access party.[398]

Some countries provide generally for monetary and non-monetary benefits although the specific types of benefits are not stated.[399]

1. Practical examples of ABS agreements

Although this study does not deal with the implementation of ABS laws, it may be useful to provide practical examples of the nature of the benefits that parties agree to especially where there is commercial utilization of the genetic resource. This section examines some of these agreements. Only one of these is an agreement under an ABS law (South Africa). Australia has proposed a model agreement under its ABS law. The rest are not agreements pursuant to any ABS law.

1.1. Typical ABS agreement

An examination of a typical elaborate ABS agreement shows a mix of monetary and non-monetary benefits.[400] The financial benefits component consists of:

- Revenue from direct sales; these are shared on a graduated basis, with the collaborator receiving a percentage of net direct sales up to a certain limit. If sales exceed that amount, additional income on a higher percentage basis accrues.

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[393] Bonn Guidelines propose that IPRs could come under both monetary and non-monetary benefits. For non-monetary benefits, IPRs are a form of transfer of technology.

[394] **India.** The NBA will lay down the conditions under which applicants may seek IPRs - Rule 14(6)(iv) of Indian Biodiversity Rules 2004. When grating approval for IPRs, the NBA may impose a benefit-sharing fee or royalty or both or impose conditions including the sharing of financial benefits – Section 6(2) Indian Biodiversity Act 2002.

[395] **Uganda (**Benefits to be shared shall include joint ownership of patents and other relevant forms of IPRs. Regulation 20(2)(i) of Uganda ABS Regulations 2005. In addition, a materials transfer agreement shall require the collector to provide for the manner of sharing of benefits arising from IPRs accruing from genetic resources. Regulation 15(2)(g) of the Regulations), **Kenya** ('Joint ownership of relevant IPRs' is listed as one of the non-monetary benefits that may be shared, Regulations 20(3)(j) and 20(4)(l), but the Kenya ABS Regulations 2006 do not indicate whether such sharing is mandatory), **Bhutan** (As part of the benefit-sharing conditions, the Competent Authority or any relevant shareholder must be recognized as a partner in IP ownership of products derived from the supplied material. Section 10(e) of the Bhutan Biodiversity Act 2003), **South Africa** (As one of the possible benefits. Section 9 of Annexure 8 to the South African ABS Regulations 2008) and **Ethiopia** (Section 19(6) of the Ethiopian Proclamation 2006)**.**

[396] **Bolivia** (The conditions for the determination of the holding of ownership of the IPRs will be included in the Access Contract. Article 36 of the Bolivian Regulations on Access 1997), **Brazil** (Mandatory benefits in the Contract for Use of Genetic Heritage and Benefit-Sharing. Article 28(V) of the Brazilian Provisional Act 2001).

[397] Australian Regulations do not provide for the vesting of IPRs.

[398] The access provider here include both access provider and Commonwealth.

[399] **Sabah** (Section 17(b)(viii) of the Sabah Biodiversity Enactment 2000 provides that the application for an access licence shall include information on the benefits, whether economic, technical, scientific, environmental, social or otherwise that may derive to the state and the concerned communities), **Hawaii** (Section 5(2)(c) of the Hawaiian Draft Bill on Bioprospecting 2007 says that benefit-sharing should provide for the distribution of monetary and non-monetary benefits to the stakeholders that may result from the exploration activities), and **Malawi** (Article 36(2)(b) of the Act and Part B of the Guidelines).

[400] The agreement is an adaption of an agreement submitted by the University of Hawaii to the Office of Information Practices in the State of Hawaii. It appears in Costanza, loc. cit. at p. 1506.

- Revenue from licensing to third parties; also on a graduated basis.
- Royalty stacking provision: this is where there are multiple patents that affect the final product. Often a number of different patented items are licensed for the development of a new product. The company developing the product will have to pay for the use of each of these patents thus adding to the cost of commercialization.[401]
- Milestone payments: these are performance-based rewarding the collaborator for competently executing its responsibilities;[402] or based on the completion of stages towards product development.

The non-monetary component consists of:

- Training in technology for both advanced scientific methods and in the use of proprietary technology.
- Visit to the company's facilities for training in technology. This is expected to improve the scientific capacity of the employees but also gives them access to professional resources that may not be available in their own laboratories.[403]

1.2. The Ethiopian Teff ABS Agreement404

It is instructive to look at the benefit-sharing terms in an agreement between the governmental authorities and a private foreign company in respect of access to a genetic resource (*Teff*) to produce food and beverage products.

The monetary benefits in the agreement are:

- A lump sum calculated by reference to a formula representing 1% of the gross income (calculated as an average over 3 designated years).
- A royalty of 30% of the net profit from the sale of basic and certified seeds of the particular varieties.
- An annual licence fee.
- A contribution of 5% of the net profits (subject to a minimum of 20,000 Euros per year) to a fund. The fund is to be used to improve the living conditions of local farming communities and for developing the business related to the resource in Ethiopia.

The non-monetary benefits are:

- Sharing of the results of the research that will be undertaken in respect of the resource.

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[401] When multiple patents are held by third parties, the royalty structure may make the deal financially unattractive: Clark V 2004 Pitfalls of Drafting Royalty Provisions in Patent licenses, *Bioscience Law Review,* cited in Charles Costanza, loc. Cit. at p. 1505. In contrast, when one company holds multiple patents involved in the process, determining final royalty allocation is simplified: Costanza at p. 1505.

[402] The maximum amount is established as a percentage of the annual funding that the biodiversity collaborator receives from the company ad can be based on a range reflecting the degree of success or progress achieved by the collaborator.

[403] The training in the collaborator's laboratory is said to be critical as the laboratory infrastructure may need updating, lab protocols need changing and this may be accomplished with the company's guidance to support different equipment and supplies. Costanza, loc cit at p. 1505. However confidentiality provisions may make less accessible the information relating to the technology: ibid.

[404] This agreement preceded the Ethiopian ABS law.

- Sharing of the knowledge or technologies that may be generated but subject to the protection of confidential business information.
- The involvement of local scientists in the research. The mode of participation is to be mutually agreed. The company is to contract out research to Ethiopian research institutions, 'as appropriate'.
- The Ethiopian Agricultural Research Institution, a party to the agreement, is to be the preferred institution to breed the resource varieties.
- Contribution to the local economy by the company establishing profitable joint venture Teff businesses in the country.
- Acknowledgement of Ethiopia as the country of origin of the resource in all publications of the company as well as in applications for the registration of Teff varieties and other IPRs over products the company will develop from the genetic resource.

1.3. The Australian model ABS agreement

Australia has also developed a model ABS agreement which sets out the following benefit-sharing terms.

Monetary benefits:

- If the purpose of the product is for use as a pharmaceutical, nutraceutical or agricultural: A payment of either 2.5% if the annual gross exploitation revenue is 500,000 – 5 million Australian dollars; or 5% where it exceeds 5 million dollars. There is no payment if such revenue is less than 500,000 dollars.
- If the purpose is for research: then a payment of 2.5% is payable if the gross exploitation revenue is more than 200,000 dollars; or 1% for the following: 100,000 to 3 million dollars; 3% if more than 3 million dollars. There is no payment if the revenue is less than 100,000 dollars.

The model agreement refers parties to the benefits set-out in the Bonn Guidelines as additional terms that may be incorporated in the agreement. However, there is an indicative list of clauses offered by way of example, as follows:

- The provider may request additional research to be conducted on field trips to access biological resources. The provider is to bear reasonable costs of this additional research with terms and conditions to be separately negotiated.
- The party seeking access will provide research funding to a local research institution to conduct research on species collected as samples or the ecosystem from which they were collected.
- For this purpose the access party will enter into a joint venture with an Australian research institution; or an Australian company or research institution to undertake bioactivity screening, preclinical and/or clinical trials or otherwise develop commercial products containing the sample or a product.
- The access party will transfer to an Australian research institution or to indigenous provider, knowledge to make use of genetic resources, including biotechnology, or knowledge that is relevant to the conservation and sustainable use of biodiversity.
- The access party will transfer to an Australian research institution technology to make use of genetic resources, including biotechnology, or technology that is relevant to the conservation and sustainable use of biodiversity. The terms of transfer are to be negotiated with the receiving

institution and should be developed on fair and preferential terms, including concessional and preferential terms.

- The access party will collaborate with Australian research institutions and contribute to scientific research and development programmes, particularly biotechnological research activities.

1.4. Agreement between the Southern African Hoodia Growers Association (SAHGA) and the Working Group of Indigenous Minorities in Southern Africa (WIMSA), March 2007[405]

This is a benefit-sharing agreement and joint venture in relation to a genetic resource – Hoodia,[406] which has uses for food, food additive and as a dietary supplement. The agreement was in the context of the Biodiversity Act of South Africa 2004. The financial benefits for the San community were based on a levy charged on each kilogram of dry, processed *Hoodia*. Calculation of the levy was based on a number of factors including a levy of 6% of the sale from the farm, as well as conditions in the fluctuating world *Hoodia* market, the need for the levy to be affordable for growers, and other equity considerations. The agreement also provided for re-evaluation after one year to ensure that the eventual amount will be fair to both sides.

1.5. Master Bio Trust agreement under the E.O. Wilson Biodiversity Foundation

Some private initiatives also provide an example of how other alternative benefit-sharing agreements can enhance ABS in relation to GRFA. The E.O. Wilson Biodiversity Foundation has created a Bio Trust which seeks to ensure fair terms between countries and companies for access to genetic resources while preserving them. A master agreement allows companies, as well as academic and research institutions to sample and analyse genes, small molecules and proteins. A portion of the revenues produced from any resulting products flows back to the country of origin for purposes of conservation. Participants in the Trust agree to participate in capacity building through technology access and/or education for source nations.[407]

1.6. Conclusions

Assessing what benefits are 'fair and equitable' may not be easy. First, the provider may not be able to assess the potential worth of a use or value of the genetic resource, despite the provision of information by the user, especially at the time of the negotiation for MATs when a commercially viable product has yet to be developed. The user itself may not know the ultimate worth of the end product. In the Hoodia agreement between SAHGA and the San community, all parties were fully aware that the original figure was agreed upon without adequate knowledge about trade volumes, without extensive calculation of likely implications of percentages for all parties and without sufficient reliable information to fix an appropriate percentage with confidence.[408] Further complications may arise where genetic resources are

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[405] The source of this information is Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors*, CBD, UNEP, 2008, at p. 92. The agreement is unpublished and there is no disclosure of the non-monetary benefits. There is also an earlier benefit-sharing and value-adding under the San-CSIR-Phytopharm-Unilever agreements: see further *ibid* at p. 89 – 93.

[406] The species are succulent plants indigenous to Southern Africa and long used to stave off hunger and thirst by the indigenous San peoples, the oldest human inhabitants in South Africa.

[407] E.O.Wison Biodiversity Foundation: www.eowilson.org.

[408] Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors*, CBD, UNEP, 2008, at p. 94.

accessed from multiple providers.[409] This difficulty could apply especially to agricultural application involving conventional plant breeding, as quantifying the contribution by the various providers to the development of a new plant variety may be impossible in most cases.

However, these considerations may not be entirely relevant for access to GRFA as generally it is expected that parties will know what they want and the benefits to be shared. Again requiring an elaborate process, including with several stakeholders, for negotiating MATs for GRFA may not be quite relevant where the potential commercial benefits are usually known and predictable. 'However, valuation of genetic resources may in some cases be very complex as such resource value differs from traditional kinds of value accorded to biological resources. It goes beyond the physical quality of the particular material. Economic advantage was sought by improving relevant qualities (breeding new varieties, choosing appropriate sites for nurturing the variety, developing soil treatments to improve the quality and amount of harvest, etc; and value to the owner of the resources or other dealer was based on a combination of factors related to the amount of material produced and sold and the price obtained. However, the use of a genetic resource may not depend on any of these qualities. Particular genetic or biochemical data or material may be valuable as a genetic resource where it is linked to properties that can be sued and replicated in other ways. Their value may depend on either or both of the micro-physical genetic material and the genetic information it contains. Their utilisation may confer a different or additional value beyond the bulk value of the particular biological resource and is not dependent on the physical quality of the material'.[410]

A clear situation where negotiating MATs may be relevant is when PGRFA involving novel traits are accessed for the profits from the products (nutraceuticals, nutritionals) may be difficult to predict. Further phased agreements - where a fresh agreement is entered into when the commercialization of the material accessed is imminent - may also be inapposite for GRFA as the purpose of the access and the benefits are usually clearly known from the outset. For this reason too it may be superfluous for access negotiations to be lengthy. Instead, standardized benefit-sharing agreements may be particularly useful and cut down on the transaction costs. Some countries already include such standard agreements in their ABS laws. A useful example is provided by the SMTA of the ITPGRFA. Under the SMTA, users of PGRFA who commercialise a product must pay 1.1% of the sales of the product (less 30%) if they do not make their product freely available for further research and breeding. The SMTA also foresees as an option a discounted rate for access to genetic resources of a specific crop where the recipient agrees to make payments based on the sale of his products belonging to the same crop independent of whether or not the product is available without restriction.

The fact that in the food and agriculture sector the number of accessions is rather large also makes standardized agreements attractive. In this situation, individual case by case bilaterally negotiated benefit-sharing agreements would simply run up transaction costs. The examples of the model agreements cited also suggest that even more elaborate benefit-sharing agreements may be amenable to standardization.

In any event, in respect of non-monetary benefits such as the transfer of technology, especially making available the results of the research and joint research, the benefits are known and not dependent upon a valuation of the product that is to be commercialised. Indeed the benefits seen in agreements voluntarily entered into - and not on the basis of ABS laws – show that most of the benefits are non-monetary in

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[409] Lyle Glowka et al, *A Guide to the Convention on Biological Diversity*, IUCN, (1994), at p. 83.

[410] This aspect reproduced from Morten Walloe Tvedt and Tomme Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD,* IUCN Environmental Policy and Law Paper No. 67/2, ABS Series No.2, 2007, at p. 76, Para. 5.2.

nature. Such benefits can also be provided for in standard agreements as an analysis of the sample agreements illustrate. These agreements reflect an acceptable framework for ABS with commercial ends. They would enhance speedy decision making, cut down on the duration of negotiations and facilitate access. This would enhance food security.

2. Other specific conditions for access and benefit-sharing arrangements

The applicant must make an application to the state authority. Most ABS laws prescribe the information that must be furnished in this application.

2.1. Information to be furnished with the application

Typical information includes:[411] matters related to the applicant, the type and quantity of the resource, the duration of the activity, geographical prospecting area, evaluation of impact on conservation and sustainable use of biodiversity, the intended use of the resource – taxonomy, collection, research, commercialization, where and how - the research and development will be carried out, local collaborators, possible third party involvement, purpose of the collection, research and expected results, kind/types of benefits that could flow from the access (including from derivatives and products arising from the commercial use and other utilization of the genetic resource), indication of benefit-sharing arrangements, budget and treatment of confidential information. Other information which may be required includes an indication of the utilization of local or indigenous TK.[412]

2.2. Approval requirements

Generally ABS laws require approval from the state for access for all purposes, typically research or commercial utilization. Some laws extend the purpose to bio-survey or bio-utilisation meaning the survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and includes characterization, inventorisation or bioassay.[413] Most ABS laws do not set out the specific activity for which access will be approved. It appears that any activity for the specified purpose requires approval.

Examples of access activities include the following:

- Locating the material ex situ or in situ;
- Simple surveying;
- Sampling;
- Collecting;[414]
- Transferring;[415]
- Exploiting[416] through breeding or biotechnology;[417]

[411] The information is similar to the indicative list under the Bonn Guidelines, Article 36.
[412] The Bonn Guidelines make explicit that permission to access genetic resources does not necessarily imply permission to use associated TK and vice versa: Article 37.
[413] **India**: section 3 (for foreigners) and 7 (for nationals) read with section 2(d), The Biological Diversity Act, 2002.
[414] **Uganda, ASEAN Framework Agreement, Sabah, Bangladesh, Ethiopia, Philippines, South Africa.**
[415] **Ethiopia.**
[416] **Hawaii**, section 1 of the Draft Bill, **Vanuatu, Nigeria.**
[417] German Research Foundation, *Guidelines for Funding Proposals concerning Research Projects within the Scope of the CBD,* p.6. See also Swiss Academy of Sciences, *ABS: Good Practice for Academic Research on Genetic Resources,* 2006, 14.

- Harvesting;[418]
- Exploration;[419] and
- Exporting.[420]

The various levels of activity may be governed by different areas of laws. For example, visiting an *in situ* location may be subject to rules of conduct for certain geographic or species-specific locations, or regarding certain protected species. Also, the requirements for different activities could vary according to the nature of the activity.

Some countries specify the factors that they consider in deciding whether or not to grant the approval.

2.3. Applicant - related requirements

Factors relating to the applicant typically include:

- Whether the applicant possesses legal capacity;[421]
- The ability of the applicant to comply with the conditions subject to which access is granted.[422]

2.4. Monitoring - related requirements

Factors relating to monitoring typically include:

- The establishment of a monitoring and auditing system;[423]
- Whether the necessary permits and authorizations have been obtained;[424]
- Whether relevant laws and regulations have been complied with or whether a commitment to do so has been given;[425]
- Bond arrangements for possible damage or harm arising from non-compliance.[426]

2.5. Environmental impact assessment

Factors relating to an assessment of the impact of the access activity on biodiversity and the environment typically include:

- Impacts of the access activity on the conservation and sustainable use of biological resources;[427] and

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[418] **Hawaii**, section 1 of the Draft Bill, **Vanuatu.**

[419] **Uganda, Brazil.**

[420] **Bhutan, South Africa.**

[421] **Guyana** (draft Regulations) **Bolivia, Andean Decision 391, Malaysian state of Sabah, Pakistan.**

[422] **Guyana** (draft Regulations).

[423] **Vanuatu**.

[424] **Guyana** (draft Regulations).

[425] **Guyana** (draft Regulations), **Vanuatu, Queensland, Bangladesh.**

[426] **Vanuatu.**

[427] **Kenya** (the Authority shall grant access 'if satisfied that the activity to be carried out shall facilitate the sustainable management and utilization of genetic resources for the benefit of the people of Kenya'), **Sabah, South Africa, Australia.**

- Impacts of the access activity on biological diversity and the environment.[428]

2.6. Requirements in relation to ILCs and other stakeholders

Factors relating to ILCs and other stakeholders typically include:

- Impact of the access activity on ILCs;[429]
- Whether PIC has been obtained from the lead agency, local community or owner of the land on which the resource is located or owner or provider of the resource;[430] or from ILCs;[431]
- Whether relevant contracts have been concluded with customary landowners or owners of TK,[432] or the lead agency, local community or owner of the land on which the resource is located or owner or provider of the resource;[433]
- Consultation with affected ILCs.[434]

3. Vetting of PIC and MATs

Some countries specify that the PIC be vetted.[435] Some countries also set out the purpose for the vetting. These include: to ensure the legality of the obligations and rights arising from the PIC;[436] to verify that the requirements of PIC are complied with;[437] to ensure that the person giving PIC has adequate knowledge of the regulations and is able to engage in reasonable negotiations about the benefit-sharing agreement, and that he has adequate time to consider the application, including time to consult with other relevant people and stakeholders (such as the traditional owners of the land on which the resource exists); and to negotiate the benefit-sharing agreement.[438] The entity responsible for the vetting varies, and might include

[428] **Guyana** (draft Regulations), **Sabah, Australia, Uganda, Costa Rica, Pakistan** (endangers any component of biodiversity)**.**

[429] **Sabah, India.**

[430] **Uganda**.

[431] **South Africa, Afghanistan.**

[432] **South Africa, Vanuatu.**

[433] **Uganda**.

[434] **Guyana** (draft Regulations).

[435] **Bolivia**, **Costa Rica**, **Pakistan**, and **Australia** (Minister to consider several matters in determining whether an access provider has given informed consent to a benefit-sharing agreement).

[436] **Bolivia.**

[437] **Pakistan.**

[438] **Australia,** Regulations 8A.10, para 2(b).

the Office of Natural Resources and the Environment,[439] the Technical Office,[440] the national inter-sector coordination body,[441] and the responsible Minister.[442]

It was noted earlier that most countries require the MATs to be vetted, although some regional and national laws do not require such vetting.[443]

4. Denial of access

There is no certainty that an applicant who satisfies all the requirements of the ABS law for access will indeed be granted access. Access may yet be denied on several bases. First, as the ABS arrangements are commercial in nature, if the terms for the access are not agreed to by the parties, the approval will not materialize. Aside from this, some laws provide the grounds upon which an approval may be denied. In any event countries are also at liberty to deny access for reasons implied in the CBD provisions. These are that the access must be for environmentally sound uses and that it furthers the objectives of the CBD.[444] What makes up such use and what will attain the objective of conservation and sustainable use of the resource is undefined and left to each country to decide. These two facets constitute restrictions to unimpeded access. Countries may include these grounds in their ABS laws as a basis to deny access for these reasons. It is noted that the CBD exhorts Parties not to place restrictions on access to genetic resources which runs counter to the objectives of the CBD. This seeks to preserve the concept of unrestricted access. This concept, as discussed earlier, prevailed at a time when genetic resources were considered as the common heritage of mankind freely available to anyone for any purpose. This has been progressively narrowed primarily in the context of the early debates in the FAO in relation to plant genetic resources.

The debate has now shifted to the CBD which deals with access in relation to all genetic resources – plant, animal, aquatic and microbial. The expectation is that states, now acknowledged as sovereign owners of their resources, will enhance and facilitate access to genetic resources. This expectation will not be realized if the grounds for denial are broad and undefined. The exercise of such subjective and uncontrolled power has the potential to hamper access.

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[439] **Bolivia** (The National Secretary's Office of Natural Resources and the Environment will watch for the legality of the obligations and rights arising from the Annex. Non-fulfilment of the Annex is a reason for the abrogation and nullification of the Access Contract).

[440] **Costa Rica** (PIC to be endorsed by the Technical Office. It should be noted that the Technical Office (TO) limits itself to endorsing the contract rather than negotiating it. But this literal reading of the GRA creates some difficulties. For example what happens if there is no third party from whom to obtain physical access? The law does not provide for negotiations with the TO. Also, if a university possesses its own *ex situ* resources and wants to make use of those resources in bioprospecting, the PIC prescribed would not be necessary? Should the TO grant the PIC then? This law does not override existing measures on access to biological resources. Thus does it mean even if an access permit is granted by the TO, an additional permit under other laws, namely Law of Wildlife Conservation be required? Otherwise, can the TO be interpreted as having the power to interfere in the negotiation process when the mandatory monetary benefits have not been considered in the contract, and the TO can demand for their inclusion? And on what grounds can the TO disapprove the contract?).

[441] **Pakistan** (Verifying the requirements of PIC by local communities to ensure that they are complied with).

[442] **Australia** (In considering whether an access provider has given informed consent to a benefit-sharing agreement, the Minister must consider whether the access provider had adequate knowledge of the Regulations and was able to engage in reasonable negotiations about the benefit-sharing agreement; whether the access provider was given adequate time to consider the application for the permit, to consult with the relevant stakeholders and to negotiate the benefit-sharing agreement. See Regulation 8A.10 of the Australian Environment Regulations 2005).

[443] **Vanuatu**, **Pakistan**, **Bangladesh** (However, the National Biodiversity Authority reserves the right to unilaterally withdraw its consent and terminate the agreement), **Guyana**, **Nigeria**, **Kenya**, and the **African Model Law** (Although the National Inter-sectoral Coordination Body is to ensure that minimum terms in the agreement are complied with).

[444] Article 15.2, CBD.

However, the interdependence of countries to access GRFA requires more, not less unimpeded access. This part of the study looks at the basis on which laws and guidelines deny access to genetic resources. It is significant that the Bonn Guidelines do not provide grounds upon which access to genetic resources can be denied or restricted. It provides instead, in rather cautionary language, that any restriction should be transparent, based on legal grounds, and not run counter to the objectives of the Convention.[445] The laws of some countries allow denial of access on the ground that it would not be in the 'best interest of the country', or 'contrary to its national interest'.[446] Such rather broadly worded grounds give the resource provider wide discretionary power to refuse approval. Such powers present a further hurdle to the free use and exchange of GRFA. However, some laws specify the grounds for denial: endemism, rarity or danger of extinction of species, subspecies, varieties or races or breeds;[447] some other grounds, in addition, allow denial if the access sought could cause adverse effects to the environment and/or human health;[448] or if the conditions in the structure or functioning of ecosystems are considered vulnerable or fragile.[449] Some also allow denial of access if ILCs object to the access 'based on cultural, spiritual, social, economic or other motives', or, if the access could have an adverse effect on the essential elements of their autonomy or cultural identity, or there is adverse impact of the access activity on their lifestyles and livelihoods.[450] Access may also be denied to genetic resources or geographical areas qualified as strategic.[451]

Certain countries take into account the issue of food security in evaluating the application.[452] Other countries take into account the sustainable management and utilization of genetic resources and the impact of the proposed activity upon the resource concerned;[453] or the objective of equitable sharing of benefits.[454] Some countries set-out the circumstances justifying denial of access.[455] Others set-out some specific unusual grounds.[456] Some specify very broad and extensive public interest criteria as well as the precautionary principle in evaluating the access application so as to guarantee desired objectives.[457]

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[445] Article 26(c) of the Bonn Guidelines.

[446] **Costa Rica, India, Pakistan, Guyana.** For **Guyana,** the NCA may refuse to grant access on the basis of factors as the Minister considers relevant, including:
(i) the report of any EIA required by the EPA;
(ii) where consideration by the local or indigenous community is required, the report of the meeting of such community conducted in accordance with the draft Regulations;
(iii) letters of protest from any members of the local or indigenous community in response to the report of the meeting referred to in (ii);
(iv) the protection of certain species from over-exploitation;
(v) the preservation of the character of the environment, including indigenous or local communities.

[447] **Costa Rica, India, Pakistan, Uganda, Bolivia, Andean Decision 391, Guyana.**

[448] **Brazil, Costa Rica, India, Pakistan, Bolivia, Andean Decision 391, Northern Territory** of Australia**.**

[449] **Costa Rica.**

[450] **Costa Rica, Pakistan.** Under the ABS law of **Sabah,** this is one of the grounds on which the NCA may review the approval already granted**.**

[451] **Costa Rica.**

[452] **Costa Rica, India, Pakistan, Bhutan.** This is in accordance with the objectives of Bonn Guidelines.

[453] **Kenya**, **South Africa, Costa Rica, India,** the Malaysian state of **Sabah** (see footnote 449)**.**

[454] **India**.

[455] The **Northern Territory of Australia** gives examples of the circumstances justifying denial of access - an intervening cyclone, bushfire or other natural disaster – that may have affected the sustainability of the biological resources in the area proposed for taking samples.

[456] **Brazil** also prohibits access if the use of the resource is for the development of biological and chemical weapons and **Costa Rica** for military, terrorist or denaturalizing purposes such as by the use of genetic use restriction technologies (GURT).

[457] **Costa Rica** specifies:
development options for future generations;
food security and sovereignty;
ecosystems conservation;

Some may deny access to those accused of irregular and unauthorized transaction and are known to have collected specimens in any country without the PIC of the Community[458] - a wide power of enforcement assistance on behalf of other countries.

Several countries do not stipulate that reasons for the denial of access should be provided to the applicant.[459] Some laws specify the need to give reasons.[460] Some countries temper these broad powers by granting to the applicant adversely affected by the denial the right to be heard. [461]

Finally, it bears reiteration that certain countries exclude altogether any foreign legal entity from applying for an access permit on its own.[462] Some require the foreign juristic or natural person must apply jointly with the locals.[463] Brazil require that an expedition to collect *in situ* samples, must be joined by a Brazilian public institution, with the latter having mandatory coordination of activities and all the institutions concerned carry out research and development activities.[464]

5. Approval - form and duration

It was earlier discussed that the approval by the state, signifying its PIC, is given in the form of a permit or a licence. Sometimes it is incorporated in an agreement or contract between the state and the applicant. National ABS laws provide variations. In several countries, PIC is given in the form of a certificate or other standard form.[465]

The ABS laws do not seem to provide for the duration of the access agreement. Such a provision may be of importance[466] especially to the applicant, along with a provision on how the agreement may be terminated, renewed or negotiated and what the terms are for a possible renewal or renegotiation. These provisions would in all likelihood be negotiated as part of the MATs. It is likely that the approval would in all probability be fairly open-ended and depend on the purpose for which the approval is given – whether for research or for commercialization. It will also depend upon the nature of the activity involved and for which the approval is given. For example, the approval may provide for trips to collect material or

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protection of human health;
improvement of quality of life of the citizens;
gender equity; and,
the objectives of conservation, sustainable utilization and fair and equitable distribution of the benefits derived from access to the genetic and biochemical elements and resources and the related TK.
Costa Rica is a member to the ITPGRFA. The Costa Rican Constitution says that 'pursuant to our judicial system, Treaties have a superior value over ordinary law and shall not be disregarded by the law'. This implies that it will facilitate access to crops in Annex 1 of the ITPGRFA in accordance with the terms of the Treaty.
South Africa has similar public element criteria that includes:
conservation of biodiversity in South Africa;
economic development of South Africa;
enhancement of scientific knowledge and technical capacity of South African people and institutions Regulations 12(1) and 13(1) of the South African ABS Regulations 2008.

[458] Article 13(3) of the **Bangladesh** Biodiversity Act 1998.

[459] **Vanuatu**, **Gambia**, **ASEAN** Framework Agreement, the **Philippines,** and **Bangladesh**

[460] **Costa Rica** providing specifying that technical, social or environmental justifications must be given for the denial.

[461] **India,** section 24(2).

[462] **Brazil** (Article 16 of the Brazilian Provisional Act 2001), **South Africa**.

[463] **South Africa**: Regulation 9(1), ABS Regulations 2008.

[464] Article 16 Para 6 of the **Brazilian** Provisional Act 2001.

[465] See earlier Chapter IV, paragraph 1. **Philippines** (PIC Certificate to be issued in the standard form set out in Annex 4 of the Guidelines), **Uganda** (PIC will be granted in the Form set out in the Second Schedule).

[466] Costanza, loc cit, at p. 1500.

samples from diverse habitats; as well as require local collaborators to provide a minimum number of samples per year.[467] Again the duration may be partial or contemplate a phased agreement. So there may be an initial approval for collection of the sample. This will end when there commercial utilization is intended in respect of the genetic resource accessed.

5.1. Specific approval conditions

5.1.a. Specification of Use

The country granting the access would need to know the use for which the genetic resource is being sought. This will enable the application to be assessed, and approved, on the basis of that use. This also provides a basis for parties to ascertain the value of the resource to determine benefit-sharing arrangements. This implies that the resource cannot be used for any other purpose.[468] As an alternative to prohibiting its use altogether, countries often seem to prefer to renegotiate additional benefit-sharing terms if the resource is put to another use; or if the resource is to be employed for an additional use.

Several countries require the declaration of use or intended use of the genetic resource to be made at the stage when the application for access is made.[469] Some also require the information about the commercial use expected to be derived from the research;[470] or the intention to commercialise any information resulting from the access activity.[471] Some are more specific and require a statement of the type and extent of such expected commercial use.[472]

Some countries require the intended use and/or purpose to be stated, not in the application, but in documents that emerge after that: such as contracts;[473] permits;[474] approval agreements;[475] material transfer agreements;[476] research agreements;[477] and Access Agreements.[478]

Some countries go further and a designated body will do a separate evaluation of the potential of the genetic resource for uses other than that for which the access is sought and alert the NCA of this fact;[479] some require the applicant to provide as well the potential uses of the resource in the application;[480] some others**,** in addition, require any known uses of the genetic resources concerned to be specified.[481] Some countries stipulate that the purposes for which the collected material can be used must be provided in the

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[467] Based on a redacted Diversa biodiversity access agreement submitted by the University of Hawaii to the State of Hawaii (Information Practices Office), see Costanza, loc cit, at 1501.
[468] The Bonn Guidelines state that permitted uses should be clearly stipulated and new application for changes or unforeseen uses should be required – Article 34.
[469] **Brazil, Pakistan, Vanuatu**, **Afghanistan, Ethiopia,** the Australia state of **Queensland.**
[470] **India,** Form I under Rule 14, item 2(h).
[471] **Sabah** section 17(b)(i)(ii)**.**
[472] **Sabah, Bangladesh** (Article 13(9)(a)(v) of the Bangladesh Biodiversity Act 1998), **Bhutan** and the **ASEAN Framework 2004** (requires disclosure of intended use in applications for obtaining PIC (for example, for taxonomy, collection, research, commercialization) - Article 6(2)(f) of the ASEAN Framework 2004).
[473] **Brazil.**
[474] **Costa Rica, South Africa** (All bioprospecting permits and integrated export and bioprospecting permits must specify the purposes for which the indigenous biological resources concerned can be used. Section 11.1, Annexure 5 to the South African ABS Regulations 2008).
[475] **India.**
[476] **Uganda, South Africa** (Section 5, Annexure 7 to the South African ABS Regulations 2008).
[477] **Guyana** (Paragraph 5, Form A, Schedule 1 to the Guyana Draft Regulations).
[478] **Ethiopia** (Article 16(6), Ethiopian Proclamation 2006).
[479] Article 12 of the Bolivian Regulations on Access 1997.
[480] **Pakistan**.
[481] **Kenya,** paragraph 2.0(b)(vii), and paragraph 2.0(d), Part III, First Schedule to the Kenya ABS Regulations.

MTA.[482] Some require MTAs to specify the purpose for which the resource concerned is to be exported and its present potential use. Export permits for research purposes other than bioprospecting must specify the non-commercial research purposes for which the resources concerned can be used.[483]

The laws of some countries require the person granted access to enter into a fresh agreement if the purpose of the use of the resource differs from that disclosed;[484] or to submit a separate application;[485] or to obtain a fresh PIC or MAT.[486] This may occur when, for example, a discovery is made in which event there is an obligation by the access permit holder to notify the relevant authority of this fact.[487]

Some countries explicitly prohibit the use for purposes other than those disclosed. There must not be any use, for bio-discovery, a sample of material given by the holder of a collection authority.[488] The prohibition applies to the entity receiving the material.[489] Some go a step further and make it an offence if the genetic resource is put to a use other than the one agreed to in the MTA.[490]

Some countries require an identification of the place of the research;[491] whilst others restrict the use of the resource to the area or territory explicitly stated in the permit.[492] Some countries require a full and accurate description of the nature and extent of the research that is to be undertaken.[493] At the same time it is noted that some countries do not require the applicant to declare the use or intended use of genetic resources.[494]

5.1.b. Transfer to third parties

Countries may prohibit or restrict the transfer to third parties of genetic resources for which access has been granted. Or they may allow the transfer subject to approval by a designated authority.[495] The transferee may be required to adhere to the same conditions as applicable to the original approval. This allows the provider country to exercise some form of control over the resources and in particular to ensure

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[482] **Uganda,** Regulation 18.

[483] **South Africa** section 84(1)(b)(v) and (vi) Biodiversity Act 2004; section 10.1, Annexure 6 to the South African ABS Regulations 2008**.**

[484] **Costa Rica and Brazil (**basic research begins to anticipate commercial or profitable purposes)**, India, Uganda.**

[485] **Bhutan** (Section 7(d), Bhutan Biodiversity Act 2003), **Hawaii** (in the event that a permit is granted for an exploration that was not classified as commercial bioprospecting, but a subsequent discovery leads to development of a commercially valuable product, the permit holder must immediately resubmit an application for a bioprospecting permit).

[486] Article 16(b)(v) read with Article 34 of the Bonn Guidelines. The Guidelines impose a duty on the users to obtain a new PIC and MAT if the uses of genetic resources is for purposes other than those for which they were acquired, or changes or were unforeseen.

[487] **Kenya, Hawaii** (the department and commission to be informed when a discovery is made so that the commission may negotiate terms of any licensing agreement that might follow).

[488] The Australian state of **Queensland.**

[489] **Queensland.** This includes the national Museum (for animal material), the national Herbarium (for plant material or fungi) and for another organism the entity stated in the benefit-sharing agreement concerning the material.

[490] **Uganda.**

[491] **Uganda** and **Vanuatu.**

[492] **Costa Rica.**

[493] **Vanuatu, Bhutan, Bangladesh** and **Sabah.**

[494] **Nigeria.**

[495] Bonn Guidelines require transfer of genetic resources to third party to obtain new PIC or to enter into similar agreements – Article 34. The Guidelines suggest the inclusion of a clause regarding transfer to third party in MAT – Article 44(f). The Guidelines also impose a duty upon the user to provide the third party with all the relevant terms and conditions regarding the acquired material and this third party has to honour all the terms and conditions passed on to him – Article 16(b)(viii).

compliance with the original agreement relating to the use of the resource and the terms for benefit-sharing. It may also ensure that the transferee is an acceptable entity to the resource provider, especially as to its ability to comply with the obligations attached to the original approval.

Most countries allow a transfer to third parties subject to express prior approval.[496] The authority is usually the same that approves the access in the first place. Sometimes, in addition, the consent of the local community/communities involved is required.[497] In one case, the person granted access for bioprospecting purposes can provide the resources or data concerned to a third party for research use only, without prior authorisation. However, this third party recipient needs prior authorisation to transfer any material to other parties.[498] In another case, consent has to be obtained not only from the competent authority but as well from the lead agency and the holders of accessory agreements.[499] Some also require consent for the transfer to third parties of the access permit or the rights and obligations under the permit.[500]

The resource to be transferred ranges from: biological resources, genetic resources[501] (some specified 'specimen'[502] and 'biochemical elements'[503]), and knowledge[504] or associated knowledge[505] and information,[506] results of research,[507] resources or data.[508]

Some countries prohibit the transfer to third parties of the resource usually by prohibiting the transfer of the source or instrument by which the approval is granted.[509]

Several countries do not address this issue of transfer to third party at all.[510] In this case it seems unclear whether, and if so, on what terms, any transfer may take place. Terms for the transfer usually imposed are

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[496] **Bolivia**, **Costa Rica** (By a separate body – the Technical Committee), **Hawaii**, **India**, **Andean Decision 391**, **Philippines**, **Bangladesh**, **Bhutan**, **Ethiopia**, **Afghanistan**, **Pakistan**, and **Uganda.**

[497] **Bangladesh** (Article 13(16), Bangladesh Biodiversity Act 1998)**.**

[498] **Philippines** (This can be done upon execution of the SMTA. There are no similar specifications in relation to access for research purposes)**.**

[499] **Uganda**. This means facilitating agreement relating to a PIC and includes a letter of exchange, MOU, or an academic or research agreement: regulation 2.

[500] **Ethiopia:** Article 17(11) of the Proclamation 2006.

[501] **Bolivia, Hawaii, Afghanistan**.

[502] **Bangladesh**.

[503] **Hawaii**.

[504] **Ethiopia** specifies 'community knowledge.

[505] **India**.

[506] **Bangladesh**.

[507] **India**.

[508] **Philippines, India** (in respect of biological resources, associated knowledge or results for monetary consideration only to foreign nationals, companies or non resident Indians requires prior approval of NBA). For Collaborative project – also for transfer of results to any person who is not a citizen of India or citizen of India who is non resident or a body corporate or organization which is not registered or incorporated in India or which has any non Indian participation in its share capital or management).

[509] **Guyana** (Research Agreement - Regulation 26, Guyana Draft Regulations), **Kenya** (access permit - Regulation 14(1), Kenya ABS Regulations 2006). **Queensland (Australia)** forbids the bio-discovery entity from allowing others to use any of the native biological material which is the subject of the agreement for bio-discovery, unless the other person is acting for the entity or is a person who uses the native biological materials for non-commercial purpose, or is a party to a benefit-sharing agreement concerning the material: section 35(2), Queensland Biodiscovery Act 2004.

[510] **Brazil,** the Malaysian state of **Sabah, Vanuatu, ASEAN Framework Agreement, Nigeria, Northern Territory of Australia**.

mainly for ensuring equitable sharing of benefits.[511] In some cases, the initial contract states the terms for the transfer.[512] Sometimes the transferee must enter into a fresh agreement for the transfer of results of any research to a foreigner or foreign entity, including a local entity with a foreign equity.[513] Sometimes there is a specific requirement for the transfer to be effected under a written agreement containing terms no less restrictive than those which are in the original permit and any relevant benefit-sharing agreements and material transfer agreements.[514]

In almost all cases the transferee steps into the shoes of the person to whom access was originally granted, except where a fresh agreement and new terms are entered into. It is quite evident that any transfer effected without the requisite authorization or in violation of the terms of the original grant will be a breach of the access approval arrangement. The authority then has the option to cancel the approval or the contract and/or seek some other remedies under the general law (such as damages, loss of profits).

Some countries provide expressly for the consequences, such as the right to annul the access contract.[515] Some require the NCA to give public notice of every approval for transfer granted by it for biological resources or associated knowledge.[516] Others require the written consent of a Minister for the sale or donation of the resource to a third party.[517]

5.1.c. Implications

The provisions especially those relating to specification of use, requiring fresh negotiations for every new use of the resource accessed, and elaborate procedures for notification to the authorities of the transfer of the resource are aimed at ensuring that the approval conditions will be adhered to, and in particular, that there is no leakage of the benefits agreed upon. They also assist the provider to track and monitor for the same purpose. However, where the use of the resource is known and does not change, these restrictions could potentially inhibit the free flow of GRFA to traditional users and breeders. Similarly procedures inhibiting the ready transfer of the resource from the person originally granted access to others, especially to bona fide researchers, breeders and developers tend to inhibit the free flow and exchange of GRFA and impede research and development.[518] In that sense, the potential to adversely impact the development of GRFA exists.

Furthermore, the ABS approaches envisage a situation where the countries of the North are the users and those of the South the providers. This may not always be the case for all GRFA. There have been extensive movements of livestock germplasm from developed to developing countries. The access of animal germplasm by the South from the North has been funded largely by public sector subsidies and through commercial market transactions, as noted earlier. If the provider countries of the North were to impose similar requirements for access, especially as regards benefit-sharing, it is difficult to gauge the

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[511] **Bolivia , Hawaii, India,** (specifies that this includes the imposition of charges by way of royalty).

[512] **Andean Decision 391**, (in the access contracts and accessory contracts), **Bolivia** (in accessory contract), **South Africa** (material transfer agreement - Section 84(1)(b)(vii) of the South African Biodiversity Act 2004), **Afghanistan** (in access permit).

[513] **India** (for collaborative research project): section 4, Biodiversity Act 2002 read with Guidelines, 4(8).

[514] **South Africa** (Section 10, Annexure 4 to the Regulations; section 11.3, Annexure 5 to the South African ABS Regulations 2008).

[515] **Bolivia**.

[516] **India.**

[517] **South Africa,** Regulations 11(2)(f)(iv) and 12(2)(f)(iv).

[518] Bonn Guidelines suggest that special terms and conditions should be established under MAT to facilitate taxonomic research for non-commercial purposes in this context – Article 16(b)(viii).

consequences on developing countries. Absent any public funding, it could impede the free flow and exchange of such genetic resources to these countries.

6. Enforcement

6.1. Monitoring and tracking

Monitoring and tracking ensures that the conditions upon which approval is granted as well as the MATs are adhered to, and that the provider is not deprived of the benefits agreed to by the use of the genetic resource supplied. Tracking may be difficult in the seed sector and the livestock sector especially when the genetic identity of the material changes, although the problem is less so where a specific species gets utilized.[519] Companies usually maintain databases to track movement of material and have restrictions on the ways the material is used as well as to whom it is sent.[520] By this they hope to avoid any adverse accusation of the misuse of the material. However, as noted earlier, it may not be possible to ascertain the benefit derived from the genetic material. In particular, it may be difficult to 'track' the contribution of factors extraneous to the genetic resource for the improved agricultural output. The physical quality of the material may be improved to derive greater economic benefits through choice of sites, developing soil treatments to improve the quantity and quality of the yield. Further, as noted earlier, valuation of genetic resources may in some cases be very complex as such resource value differs from traditional kinds of value accorded to biological resources.

Various modalities exist in national ABS laws and policies to enforce compliance. At the heart of these are those relating to monitoring and tracking. These consist of the following:

- An obligation, in applications for IPRs,[521] to disclose the country of origin of the genetic resource[522] and holders of associated TK[523] and/or PIC524 to ensure PIC and MATs provisions

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[519] Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors,* (CBD, UNEP, 2008). An example of the utilization of a specific species is the case of '*Hoodia.* In such cases there are usually well defined tracking mechanisms and parties take the responsibility to ensure the specific use, as agreed (*ibid.* at pp. 28-29).The authors also note the inefficacy of tracking and monitoring physical material through the use of bar codes; and that genomic content of samples should be covered in agreements; and IPRs and other rights are much more difficult to manage for data compared with physical entities such as pieces of DNA or biological molecules (at p. 30). Further as genetic resources are now being used in various forms ranging from extracted DNA to various types of sequence data that are readily copied and can be used for a variety of purposes, tracking genetic resources would have to provide a means for providers to track the uses of the data and information derived from their genetic resources. This task of tracking successive uses of such information is complex but theoretically feasible: Garrity, Thompson, et al, *Studies on Monitoring and Tracking Genetic Resources*, UNEP/CBD/WG-ABS/7/INF/2 at p. 7.

[520] *Ibid*.

[521] Or for product registration as is proposed in the negotiations for an international regime on ABS under the CBD. The proposal is for a certificate of compliance.

[522] **Bolivia** (Secretarial Resolution from the NCA which confirms the Access Contract. Seventh clause of the Final Provisions of the Bolivian Regulations on Access 1997), **Brazil** (The person applying for IPRs must inform the origin of the genetic material and the genetic knowledge and the associated TK. Article 31 of the Brazilian Provisional Act 2001), **Costa Rica** (Applicant must always provide the certificate of origin issued by the Technical Office and the PIC. Article 80 of the Costa Rican Biodiversity Law 1998 and Article 25 of the Rules for Access 2003. The National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office before granting protection of intellectual or industrial property to innovations involving components of biodiversity. Article 62 of the Costa Rican Biodiversity Law 1998), **India** (Applicant required to give information of the biological resources including the geographical location and the source from which the biological resources are collected. Form III of the Indian Biodiversity Rules 2004 and S25(1)(j) of the Indian Patent Act 1970 (amended 1999 & 2002)), the **Andean Decision 391**(To give registration number of the access contract and to supply a copy of it. Third Complementary Provisions Decision 391; Article 26(h) and (i), Decision 486. Article 26 of Decision 391 states that the access to and transfer of technology which are subjected to patents or other IPRs must be in compliance with their Subregional and complementary national provisions. Decision 486, the Common Intellectual Property Regime 2000 is one of them), the **Philippines** (The Bioprospecting Undertaking requires the resource user to declare, in all relevant applications for IPRs or for

have been complied with.[525] In addition to such obligations under ABS laws, the PVP laws of some countries require the applicant to disclose information relating to the source of genetic material of the variety for which breeder's rights are sought,[526] while the PVP laws of some other countries require the country of origin to be registered in a national register;[527]

- An obligation by the resource user to deposit specimens at designated local institutions;[528]
- An obligation by the resource user to submit notes, periodic status reports[529] and/or other relevant material.[530]

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product development or marketing, the country from which the biological resources used for developing the product came. Section 5 of the Philippines Guidelines for Bioprospecting 2005), **Bhutan** (The applicant shall notify the Competent Authority prior to applying for IPRs relating to the collected material or IPRs relating to an invention which is based on associated TK obtained in Bhutan. Further, the applicant has to identify the nature of the legal rights which the applicant may seek over the collected resources, derivatives of the collected resources, and innovations that are derived from those resources, including any IPRs. Section 7(f), Bhutan Biodiversity Act 2003), and **Ethiopia** (The access permit holder is obliged to recognise the locality where the genetic resource or community knowledge accessed from as origin in the application for commercial property protection of the product developed therefrom. Article 17(14) of the Ethiopian Proclamation 2006).

[523] **Brazil** (Article 31 of the Brazilian Provisional Act 2001), **India** (Form III of the Indian Rules and S25(1)(j) of the Indian Patent Act 1970 (amended 1999 & 2002)), **Bhutan** (Section 7(f), Bhutan Biodiversity Act 2003), **Ethiopia** (Article 17(14) of the Ethiopian Proclamation 2006) and the **Andean Decision 391** (Article 26(h) and (i), Decision 486).

[524] **Costa Rica** (Article 62 of the Costa Rican Biodiversity Law 1998), **Pakistan** (Section 15 (2B) of the Patent Ordinance 2000. Illustrated in Pakistan Third National Report to the CBD dated 28 November 2006), **African Model Law** (Require to obtain the PIC of the original providers prior to applying for any form of IP protection over the biological resource or parts or derivatives thereof or over a community innovation, practice, knowledge or technology - Article 8(1)(v)).

[525] Bonn Guidelines encourage Parties to take measures in supporting compliance with PIC and MAT. One of the measures suggested is the disclosure of the country of origin of the genetic resources and the origin of TK, innovations and practices of ILCs in applications for IPRs – Article 16(d)(ii). This reflects Article 55(c) of the Bonn Guidelines which identifies the IPRs application process as a monitoring mechanism.

[526] **Bangladesh** (applicants must provide the origin of biological and genetic resources and related intellectual and cultural practices used in the innovation - Article 10(2) of the Bangladesh draft PVP Act); **India** (every application to contain a complete passport data of the parental lines from which the variety has been derived along with the geographical location in India from where the genetic material has been taken and all such information relating to the contribution, if any, of any farmer, village community, institution or organisation in breeding, evolution or developing the variety - Section 18(1)(e) of the Indian PVPFRA); **Malaysia** (every application to contain information relating to the source of the genetic material or the immediate parental lines of the plant variety - Section 12(1)(e) of the Malaysian PVP Act); **Pakistan** (every application to contain a description of the variety, setting forth its novelty, parentage/pedigree and breeding history - Section 15(b) of the Pakistan PBR Law); **Philippines** (every application to include exhibits of the detailed origin and breeding history of the variety, including the source of the germplasm - Section 92 of the Philippine PVP IRR).

[527] **Brazil** (the National Register of Protected Plant Varieties shall record, inter alia, the country of origin of the plant variety - Article 20 of the Brazilian PVP Law).

[528] **Brazil** (Article 16.3 of Brazilian Provisional Act 2001), **India** (Guideline 4(6) of the Indian Guidelines for Collaborative Research Projects 2006), **Guyana** (In addition, where specimens have to be sent overseas for identification, they must be returned to Guyana within a year), **Kenya**, the **Philippines**, and **Uganda**.

[529] Bonn Guidelines suggest that the parties establish requirement of reporting to promote accountability - Article 53(a).

[530] **Guyana** (under the Guidelines - field notes, interim report, final report, relevant audio, audio-visual or photographic material; under the draft Regulations - quarterly report of the collections made, final report, relevant audio, audio-visual or photographic material, information on the area of collection and the collector, list of institutions that have used or are using Guyanese species), **Kenya** (records of all intangible components of plant genetic material, quarterly reports on the status of research, semi-annual status reports or a final status report on the environmental impacts of any ongoing collection), the **Philippines** (for bioprospecting - Annual Progress Report together with the required certifications and other proofs of compliance; for non-commercial scientific research - copies of research outputs), **South Africa** (for bioprospecting - annual status reports; for research other than bioprospecting - status reports either on an annual basis or on timeframes determined by the issuing authority), **Ethiopia** (periodic progress and status reports), the **Northern Territory** (bioprospector to keep the issuing authority informed of the samples collected), **Costa Rica** (final results of the basic research, bioprospection or the scientific papers and publications derived therefrom), **Hawaii** (periodic reports on the use and location of samples collected under the permit), **Pakistan** (regular status report of research and development), and **Uganda** (regular research and development status report).

- The establishment and maintenance by the authority granting access of a register of the relevant documentation;[531]
- An obligation by the resource user to keep records for monitoring purposes;[532]
- An obligation to adhere to compliance codes established by the competent national authority;[533]
- An acknowledgment of the origin of resources and TK;[534]
- An obligation to furnish evidence of PIC of the country of origin for the import or export of any biological resources;[535]
- An obligation to declare and furnish evidence of the lawful acquisition from the country of origin of genetic resources in transit, at the point of entry and exit and in any other part of the country as may be required;[536]
- Other monitoring measures of resource users by the national authority;[537]

6.2. Offences and sanctions

Most countries make it an offence to access genetic resources without the requisite permits, consent or agreement.[538] In some countries, it is also an offence to attempt to obtain access while disqualified from

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[531] **Guyana** (under the draft Regulations - Register of Research Agreements maintained by the EPA), **Kenya** (register of all access permits granted maintained by the National Environment Management authority), **Queensland** (register of collection authorities maintained by the chief executive of the department in which the Nature Conservation Act 1992 is administered; the register of benefit-sharing agreements maintained by the chief executive of the department administering the Gene Technology Act 2001 to ensure compliance with benefit-sharing agreements entered into), the **Northern Territory** (the CEO of the Agency administering the Act to maintain a register containing information about permits issued or declined to be issued, samples taken, details of samples lodged with or transferred to other parties, benefit-sharing agreements and certificates of provenance), and **Vanuatu** (the Director of the Department responsible for the environment to maintain an Environmental Registry of all records relating to applications, permits and approvals). In addition, **Vanuatu** requires the applicant to establish a monitoring and auditing system to verify all activities undertaken by the applicant before access is granted.

[532] **Queensland** (the biodiscovery entity that has entered into a benefit-sharing agreement must keep each record or document evidencing the results of biodiscovery research carried out under the agreement for 30 years).

[533] **Queensland** (compliance code and collection protocols for taking native biological material under a collection authority).

[534] **Brazil** (origin of TK must be acknowledged in all publications, uses, exploitations and disseminations), **Costa Rica** (origin of resources must be acknowledged by providing evidence of such origin and the related knowledge in any publication, procedure or further use of them), **India** (any publication relating to knowledge associated with biological resources from India shall acknowledge the holders from which such knowledge was obtained).

[535] **Pakistan,** Article 4(3), Draft Legislation 2004**.**

[536] **Uganda**.

[537] **South Africa** (monitoring of permit holders by the issuing authority to ensure compliance with permit conditions), **Afghanistan** (appointment of inspectors for the purposes of ensuring compliance with the Act and its regulations), **Bangladesh** (ensuring compliance with the minimum conditions in agreements), **Bhutan** (monitoring compliance with access permits granted), **Ethiopia** (the Institute shall follow up through mechanisms such as inspection, periodic reports by access permit holders and any other mechanism deemed appropriate) on the execution of access agreements), **Queensland** (appointment of inspectors for monitoring purposes), **Bolivia** (the NCA, the Prefectures, the National Support Institution and the Director of Protected Area where applicable, have the obligation to ensure compliance through an elaborate and complex process. The Prefectures inspect the access activities, evaluate the reports, supervise compliance with the terms and conditions of the Access Contracts, institute preventive measures in the event of infringement and report to the NCA; the NCA will act upon evaluation by the Body of Technical Advice or report by the Director of Protected Areas and investigation carried out by the National Support Institution; the National Support Institution has a duty to collaborate with NCA in the follow-up and control of access activities and submit periodical reports; the Director of Protected Areas is responsible for the follow-up and control of access activities carried out in the area concerned), **Brazil** (the accredited institution will, in coordination with federal entities, assist in monitoring access activities and shipment and implementation of MTAs and benefit-sharing agreements), **Costa Rica** (monitoring by the Technical Office), **India** (NBA to periodically monitor compliance of conditions on which the approval was accorded), and **Uganda** (National Environmental Management Authority to collaborate with lead agencies to ensure compliance with the Regulations; lead agencies to monitor the application and use of genetic resources).

doing so.[539] Certain countries make it an offence to supply false or misleading information, or to fail to supply information, in access applications.[540] Most countries also make the breach of access conditions and/or benefit-sharing terms an offence.[541] Some countries make it an offence to export the resources accessed without complying with the requirements governing export.[542] Where the resource user is required to keep records, failure to do so may amount to an offence.[543]

Sanctions for non-compliance with ABS laws[544] may include written warning/show cause,[545] fines,[546] imprisonment,[547] and/or penalty units.[548] Several countries disqualify offenders from seeking subsequent access.[549]

In some countries, the access approval or agreement may be suspended or rescinded.[550] In some countries, an order may be made for the forfeiture of property or any deposit paid or any genetic resource collected in contravention of the relevant laws.[551]

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[538] **Guyana** (All references here are to the draft Regulations as the Guidelines do not prescribe any offences or penalties), **Nigeria**, the **Philippines**, **South Africa**, **Bhutan**, **Ethiopia**, **Malawi**, **Queensland**, the **Northern Territory**, **Costa Rica**, **Sabah**, **Uganda**, and **Vanuatu**.

[539] **Guyana**. A person is disqualified if he commits an offence under the law. see under 'Sanctions' below.

[540] **Queensland**, the **Northern Territory**, **Costa Rica**, **Sabah**, and **Uganda**.

[541] **Guyana** (Use of resources accessed and other associated material or information other than in accordance with the Research Agreement), the **Philippines** (Breach of the provisions of the Bioprospecting Undertaking), **South Africa** (Performing the activity for which the permit was issued in contravention of the permit conditions), **Afghanistan** (Breach of conditions of a licence, permit, authorisation or order issued under the Act), **Bhutan**, **Ethiopia**, **Malawi** (Use of natural resources otherwise than in accordance with the Act), **Queensland**, the **Northern Territory** (Breach of permit conditions or benefit-sharing terms), **Bolivia**, **Costa Rica** (Non-fulfilment of agreements and commitments, including violation of PIC and MAT), **Pakistan** (Violation of MATs), **Sabah** (Violation of provisions or any agreed terms under the access licence if public interest so demands), and **Uganda** (Non-respect of the clauses of an agreement or access permit).

[542] **Guyana**, **South Africa**, and **Sabah** (Removal of biological resources out of the state).

[543] **Queensland**, and the **Northern Territory**.

[544] Bonn Guidelines allows Parties to take appropriate effective and proportionate measures for violations of national legislation and administrative measures implementing the ABS provisions, including sanctions such as penalty fees set out in contractual agreements - Article 60 and 61.

[545] **Bangladesh**, **Bolivia**, **Brazil**, **Pakistan.**

[546] **Guyana**, **Nigeria**, the **Philippines**, **South Africa**, **Afghanistan**, **Bangladesh**, **Bhutan**, **Ethiopia**, **Malawi**, **Bolivia**, **Brazil**, **Costa Rica**, **India**, **Pakistan**, **Sabah**, **Uganda**, **Vanuatu.**

[547] **Guyana**, **Nigeria**, the **Philippines**, **South Africa**, **Afghanistan**, **Bhutan**, **Ethiopia**, **Malawi**, **India**, **Sabah**, **Uganda**, **Vanuatu.**

[548] **Queensland.**

[549] **Guyana** (disqualified from seeking access for a period of not less than 12 months upon first offence; permanently disqualified upon second offence), the **Philippines,** and **Pakistan** (perpetual ban on access), **Bangladesh** (perpetual ban on prospecting), **Bolivia** (ineligibility to request new access).

[550] **Guyana** (suspension or rescission of Research Agreement), the **Philippines** (cancellation or revocation of the Bioprospecting Undertaking), **Bangladesh** (cancellation or revocation of the permission for access), **Ethiopia** (cancellation of the access permit; suspension or termination of the access agreement), **Malawi** (the Genetic Resources and Biotechnology Committee of Malawi is empowered to withdraw certificates without notice or reasons), **Bolivia** (suspension of access activities; revocation of authorization), **Brazil** (suspension or cancellation of the register, patent, licence or authorization; embargo of the activity), **India** (withdrawal of access approval and revocation of written agreement), **Pakistan** (withdrawal of consent and termination of agreement and/or further use of the resources concerned), **Sabah** (withdrawal of consent and termination of access licence), **Uganda** (revocation of access permit).

[551] **Nigeria** (confiscation of equipment, instruments or any other similar things used by the offender in committing the offence), the **Philippines** (forfeiture of rehabilitation/performance bond), **Bangladesh** (confiscation of collected specimens, equipment, document or any information recorded), **Bhutan** and **Ethiopia** (confiscation of genetic resources), **Bolivia** (preventive or final confiscations of the assets and/or instruments of the transgressor), **Brazil** (seizure of samples, instruments and products), **Pakistan** (confiscation of collected specimens and equipment), **Uganda** (confiscation of genetic resources or equipment).

Several countries provide for the suspension or cancellation of IPRs as sanctions for breach of the access law.[552]Some countries follow the 'name and shame' route and may require that the offence be publicized.[553]

There are other sanctions contemplated by some laws. Some countries have extensive sanctions. A clear example is Brazil which provides that the Contracts for Use of Genetic Heritage and Benefit-Sharing shall be considered null and void when they are signed contrary to the provisions of the Provisional Act and its complementary legislation. In addition, it also provides for the following sanctions: suspension of the sale of product derived from the sample of the genetic heritage component, partial or total closure of the business or undertaking, loss or reduction of fiscal incentives and benefits granted by the government, loss or suspension of the right to receive financing from an official financing agency, 'intervention in the establishment', and prohibition of entering into contracts with the Public Administration.[554] It also provides for the payment of at least 20 per cent of the gross income obtained from the commercialization of the product or of the royalties obtained from third parties as a result of economic use of a product or process developed from the genetic resources or associated TK accessed in violation of the law.[555] **India** imposes heavier sanctions on breaches by or for the benefit of foreigners, for example on foreigners who fail to obtain NBA's approval before access, or on locals who fail to seek approval before transferring knowledge or research and material to foreigners.

7. Dispute settlement[556]

Several countries provide for dispute resolution mechanisms. Some set-out a comprehensive dispute resolution mechanism for alleged violations of the terms and conditions of the access agreement.[557] Conflicts arising out of the interpretation and implementation of benefit-sharing terms are encouraged to be settled amicably between the resource user and resource provider(s) concerned.[558] Some others provide that a court of law or any specialized court or tribunal duly established, having original jurisdiction, hear disputes arising under the relevant law.[559] Also, contemplated by some are alternate dispute resolution processes for resolving environmental disputes, including the prescribing of criteria for the appointment of qualified persons to act as a mediator, arbitrator or facilitator.[560]

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[552] **Brazil** (This is one of the sanctions which may be imposed for any act or omission that violates the rules provided for in the Provisional Act and other relevant legal provisions. Article 30(VIII) (IX) of Brazilian Provisional Act 2001), and **Pakistan** (Certificates of Intellectual Property are void if biological resources were obtained in violation of the law or MATs. Article 4.6 of the Pakistan Draft Law on Access 2004).

[553] **Guyana** (the court may make an order directing the offender to publish, in the prescribed place and manner, the facts relating to his conviction), the **Philippines** (the violation shall be published in national and international media and shall be reported by the agencies to the relevant international and regional monitoring bodies), **Bangladesh** (the violation shall be publicised to national and international media and shall be reported by the National Biodiversity Authority to the secretariats and implementing agencies of all relevant international agreements and regional bodies), **Pakistan** (violation shall be publicised in the national and international media and shall be reported by the competent national authority to the secretariats of relevant international governments and regional bodies).

[554] Article 30(1) of the Provisional Act 2001.

[555] Article 26, Provisional Act 2001.

[556] Bonn Guidelines suggest settlement of disputes should be resolved in accordance with the relevant contractual arrangements on ABS and the applicable law and practices –Article 59. The Guidelines do not recommend the type of dispute settlement.

[557] **Philippines**. Formal complaints of such violations (particularly the procurement of PIC and the collection of materials) may be lodged by any member of resource provider groups with any of the implementing agencies. Upon a prima facie finding of violation, the agency concerned will undertake a fact finding mission and will report its findings to the NCA not later than 30 days after the fact finding mission. Any person may provide information to the implementing agencies regarding such violations.

[558] **Philippines.**

[559] For **Bhutan**, under its Biodiversity Act, Section 48(a).

[560] **Vanuatu** (to date no such regulations have been made, section 45(1)(c)).

Some countries provide that dispute resolution mechanisms are to be set-out in the relevant agreement.[561] Some do not provide for dispute resolution mechanisms but provide for who is to provide evidentiary proof in support.[562]

[561] **Uganda** (MTA to include modes of settling disputes arising from the interpretation and implementation of the agreement, including an arbitration clause), **Ethiopia** (access agreement to specify, among other things, dispute settlement mechanisms), **India** (access agreement to specify legal provisions including arbitration).

[562] **Bangladesh** merely states that in cases of disputes and conflicts at the national or international level, the National Biodiversity Authority will be responsible for providing legal evidence of prior community knowledge relating to biological and genetic resources of the country and the knowledge, culture and practice related to these resources.

Appendix I

COUNTRIES AND REGIONAL LEGAL INSTRUMENTS EXAMINED IN THE STUDY

Asia Pacific
- Afghanistan
- Bangladesh
- Bhutan
- India
- Malaysia (state of Sabah)
- Pakistan
- Philippines
- Thailand
- Vanuatu

Africa
- Ethiopia
- Gambia
- Kenya
- Malawi
- Nigeria
- South Africa
- Uganda

Latin America
- Bolivia
- Brazil
- Guyana

Central America
- Costa Rica

Other countries
- Australia
- Portugal
- United States of America (state of Hawaii)

Regional laws and arrangements

- Andean Community
- ASEAN Framework Agreement on Access to Biological and genetic Resources
- Organisation for African Unity (Model Law and a Convention)

Guidelines

- Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization
- Guidelines for Funding Proposals Concerning Research Projects within the Scope of the CBD, issued by German Research Foundation
- Access and Benefit-Sharing: Good practice for academic research on genetic resources, issued by Swiss Academy of Sciences

Appendix II

LAWS AND GUIDELINES EXAMINED IN THE STUDY

Country/Region	Law
Afghanistan	• Environment Act 2005
Australia	• Environment Protection & Biodiversity Conservation Act 1999 • Environment Protection & Biodiversity Conservation Regulations 2000 • Biological Resources Act 2006 (Northern Territory of Australia) • Biodiscovery Act 2004 (Queensland)
Bangladesh	• Biodiversity and Community Knowledge Protection Act 1998
Bhutan	• Biodiversity Act 2003
Bolivia	• Supreme Decree No. 24676, Regulation of Decision 391 on the Common Regime for Access to Genetic Resources (21 June, 1997)
Brazil	• Brazilian Provisional Act No.2, 186-16, 23.8.01
Bulgaria	• Biological Diversity Act State Gazette No. 77/9.08.2002
Costa Rica	• Biodiversity Law 1998 • General Rules for the Access to the Genetic and Biochemical Elements and Resources of the Biodiversity Decreto 020 2003 MINAE 15.12.2003
Ethiopia	• Proclamation to Provide for Access to Genetic Resources and Community Knowledge and Community Right 2006
Gambia	• National Environment Management Act No. 13, 1994
Guyana	• Environment Protection Act 1996 • Environmental Protection (Bio-Prospecting) Regulations 2001 (Draft) • Guidelines for Biodiversity Research
India	• Biological Diversity Act 2002 • Biological Diversity Rules 2004 • S.O.1911(E) Guidelines for International Collaboration Research Projects Involving Transfer or Exchange of Biological Resources or Information
Kenya	• Environment Management and Coordination Act 1999 • Environmental Management & Co-ordination (Conservation of Biological Diversity & Resources, Access to Genetic Resources & Benefit Sharing) Regulations (2006)

Malawi	• Environment Management Act 1996 • Procedures and Guidelines for Access and Collection of Genetic Resources of Malawi 1996
Malaysia	• Sabah Biodiversity Enactment 2000
Nigeria	• Federal Environmental Protection Agency Decree 1988 (Amendment Decree 1992 and 1999) • National Park Service Decree 1999
Pakistan	Legislation on Access to Biological Resources and Community Rights 2004 (Draft)
Philippines	• Wildlife Resources Conservation and Protection Act 2001 • DENR-DA-PCSD Administrative Order No.1: Joint Implementing Rules and Regulations Pursuant to Republic Act No. 9147 • Joint DENR-DA-PCSD-NCIP Administrative Order No. 1 of 2005: Guidelines for Bioprospecting Activities in the Philippines • Executive Order 247: Guidelines for Bioprospecting Activities • DENR Admin Order No. 96-20: Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources
Portugal	• Decree-Law No. 118/2002 April 20, 2002
South Africa	• National Environmental Management: Biodiversity Act 10 of 2004 • Regulations on Bioprospecting, Access and Benefit Sharing (Feb, 2008 in force)
Uganda	• The National Environment (Access to Genetic Resources and Benefit Sharing) Regulations 2005 • The National Environment Statute 1995
United States of America	• Hawai'i – A Bill relating to Bioprospecting 2007 (Draft)
Vanuatu	• Environmental Management & Conservation Act 2003
Andean Community (Bolivia, Colombia, Ecuador, Peru, Venezuela)	• Decision 391 Common Regime on Access to Genetic Resources (adopted in 1996) • Decision 486: Common Intellectual Property Regime (Dec 2000) • Decision 523: Regional Biodiversity Strategy 2002
ASEAN (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand,	• ASEAN Framework Agreement on Access to Biological and Genetic Resources 2004 (revised draft)

Vietnam)	
Organization for African Unity (53 African Countries)	• Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources 06.10.1998
Convention on Biological Diversity	• Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization
German Research Foundation	• Guidelines for Funding Proposals Concerning Research Projects within the Scope of the CBD
Swiss Academy of Sciences	• Access and Benefit Sharing: Good practice for academic research on genetic resources