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# **Benefit Sharing of Genetic Resources The Convention on Biodiversity, The Bonn Guidelines and Emerging ABS Frameworks**

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# **BENEFIT SHARING OF GENETIC RESOURCES**

The CBD, The Bonn Guidelines, and Emerging ABS Frameworks

## WHAT IS ACCESS AND BENEFIT SHARING?

Access and Benefit Sharing (ABS) issues within the context of genetic resources<sup>1</sup> comprise a substantial portion of the current debates regarding the formation and adoption of intellectual property regulatory frameworks. Access in this context refers to the ability of individuals to acquire, exchange, or use genetic resources for a multitude of purposes, not necessarily limited to commercial application. However, benefit-sharing issues are explicitly (but not only) within the context of commercialisation; financial incentives to access the genetic resources for commercialisation are substantial, particularly if there is sufficient demand for the resultant product. Yet, if someone other than the party who successfully commercialized originally held the resource previous to its commercialisation, concerns arise as to whether or not those who originally held the resource should receive a portion of the monetary (or non-monetary) benefits accrued from its sale.

The relevance of access and benefit sharing is significant due to the large amount of genetic resources that have commercial viability in a number of formal sectors, including (but not necessarily limited to) pharmaceuticals, biotechnology, seed, horticulture, botanical medicine, cosmetic and personal care, and food and beverage sectors. Of the 25 best selling drugs worldwide in 1997, 42 percent of the sales of these drugs were of those derived from plant genetic resources. Similarly, out of the top 150 drugs prescribed in the United States, 57 percent of the prescriptions filed for these drugs were for pharmaceuticals that contained at least one major compound derived from compounds sourced from biological diversity<sup>2</sup>.

This commercial aspect of genetic resources has been the driving force behind the search for as yet undiscovered (at least by industry) genetic resources that have significant commercial potential. However, in this search for genetic resources, the methodology of some firms searching for genetic resources for commercial purposes has been an issue of contention. More specifically, the concerns relate to how these resources are acquired, and what the formal relationship between those who have historically held these resources and associated indigenous knowledge (IK), and those parties who seek this knowledge for commercial purposes is.

The majority of the genetic resources that are of interest to industry are located between the two tropics. 44% of all species of higher plants are confined to 25 “hotspots” of biological diversity. These 25 areas only account for 1.4% of available land on Earth<sup>3</sup>. While not all the areas are within the tropics, those areas within the tropics have the

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richest concentration of biodiversity. Much of the focus of “bioprospectors”, i.e. those parties looking for genetic resources with commercial potential, has been in these areas. Clearly, in light of the trends exhibited regarding the bioprospecting activities of the formal sector, legislation in these areas is required to ensure that if these resources and associated IK are acquired from communities, some sort of benefit sharing agreement should exist, and guidelines from which to develop such legislation are required. But what are these guidelines? What should policy and legislation at a national level incorporate in terms of principles and elements?

### WHAT ARE THE RELEVANT REGULATORY INSTRUMENTS?

When considering ABS, there are four main fora that require attention; we will consider the salient features of each briefly in Table1:

Table 1: Important international agreements on ABS

<b>Organization</b>	<b>Agreement</b>	<b>Main Features</b>
World Trade Organization (WTO)	Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)	Flexibility of TRIPS Article 27.3(b) may allow member states to incorporate ABS-“friendly” provisions. Is “legally” enforceable via the WTO dispute settlement mechanism.
Food and Agriculture Organization (FAO)	International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGR)	Provides access to 64 crops via a multilateral system, but not for commercial reasons. Legally binding but lacks strong enforceable mechanism.
World Intellectual Property Organization (WIPO)	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC); Substantial Patent Law Treaty (SPLT)	The IGC mainly attempts to establish Prior Art via the creation of IK database and mirrors the CBD objectives. However, the ongoing negotiation on SPLT could potentially subvert these efforts due to the broad rules for patenting <sup>4</sup> ; it may present and the asymmetries it has with the Bonn Guidelines.
United Nations Environmental Program (UNEP)	Convention on Biological Diversity (CBD)	Presents best practices for ABS via the Bonn Guidelines, which is voluntary; not legally binding, yet expected to be influential in the drafting of domestic regulation.

### CBD AND THE BONN GUIDELINES

The formalisation of concerns relating to ABS can be traced back to the 1992 Earth Summit in Rio de Janeiro, with the adoption of the Convention on Biodiversity (CBD). Of course, the issues relating to the ABS of genetic resources predate the CBD, but the Convention was the first to explicitly state its relevance within the context of PGR in an international framework. That said however, the CBD, while legally binding, does not

serve as a substitute for national legislation. It is a terms of reference for best practice, and it is hoped that CBD member states will “endeavour” to take reforms within their national legislation to become more in line with what the CBD outlines; unlike the WTO, the UN lacks a system of enforceability. In essence, what the CBD has achieved is the facilitation of a shift from the common opinion that genetic resources are part of the common heritage of humanity, to a regime that recognises these resources as being subject to the sovereign ownership of the nations within whose boundaries they lie.

**BOX 1: The Objectives of the Convention on Biological Diversity**

- The conservation of biological diversity;
- The sustainable use of its components;
- The fair and equitable use of the benefits arising out of the utilisation of genetic resources.

Of these three objectives, the third is particularly relevant to our current discussion. In particular, Article 15 of the CBD is of significance here, as it refers to ABS issues explicitly.

**BOX 2: The Main Aspects of Article 15 of the CBD**

- Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
- Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
- Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

The sixth meeting of the Conference of Parties to the CBD in April 2002 (COP 6) deliberated on the interpretation of Article 15, and arrived at Decision VI/24. This decision brought forth “the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation”. The Bonn Guidelines are voluntary, but do comprise the first widely accepted criteria for the licensing of access to genetic resources and they are expected to be influential in the formation of national legislature. Appendix I of the Guidelines offers a detailed list of provisions that should be included in any Material Transfer Agreement (MTA), which is relevant considering one of the goals of the Guidelines is to facilitate a harmonisation of the way that MTAs are created. However, this is not to say that these rules are exhaustive. Indeed, when one considers the wide variety of circumstances that exist regarding how communities hold these resources and in identifying exactly who is the true holder, any set of guidelines must be considered as being, at the most, suggestive.

**BOX 3: The Main Provisions of the Bonn Guideline**

- The facilitation of prior informed consent of both the national government of the country of origin of the resource for transmittal as well as indigenous and local communities;
- The development of mutually agreed terms to facilitate legal certainty and the minimisation of cost;
- The specification of non-monetary and/or monetary benefits the collector will provide, and whether, and under what conditions, the collector may transfer the collected genetic resources to another party.

## THE KEY PRINCIPLES OF ACCESS AND BENEFIT SHARING

### **Prior Informed Consent (CBD Article 15.5)**

Prior Informed Consent (PIC) in the context of ABS can be broadly defined as a criterion that explicitly states that the original holders of the PGR, the state, or landowners have agreed to allow the resource to be used by another party. That is, if resources are to be exchanged across boundaries, they will mobilise if and only if there exists an agreement or statement that ensures that those originally holding the resource are indeed aware and in agreement that the resource can be provided to an outside party. It is, in essence, to recognise those original holders as the keepers of the resource by ensuring that their permission has been granted before any resources are taken (or provided) by them. More explicitly, PIC in the form of regulation may require that:

- National governments establish an authority for PIC;
- Specific terms are provided to determine standards for what information must be given to the holders;
- Local community participation in PIC (i.e. individual holders, representatives of these individuals, entire communities, or in some cases, the state).

### **Mutually Agreed Terms (CBD Article 15.4)**

Mutually Agreed Terms (MAT) define the terms and conditions by which any agreement relating to the transfer of PGR from holders to those wishing to acquire them are to adhere to. They can include provisions on a number of issues:

- Continuing monetary benefits to the original holders;
- Technology transfer, training, or research;
- Requirements on reporting how the resources are being used by the parties who acquire the PGR;
- Defining what forms the IPRs will have over the resource;
- Recognition of where the resources came from, not only in terms of geography but also in terms of parental lineage (this is referred to as “full disclosure”);
- Defining what benefits the original holders will receive as a result of the transfer.

### **Material Transfer Agreements (Bonn Guidelines Appendix I)**

Material Transfer Agreements (MTAs) have been defined as those agreements that establish standards for the transfer of biological resources for research and possible commercialisation in exchange for benefits to the party recognised as the supplier. Generally, MTAs usually grant the recipient of the material the right to apply for patents if any of the material has commercial potential. These agreements are often implemented by assuring the supplier a fixed percentage of the revenues acquired from the commercialisation of a product that had resulted from the raw genetic material provided, combined with a fixed amount for the bulk of all genetic resources accessed. The actual

remuneration varies from agreement to agreement, as do the precise terms of the remuneration. While the precise details of agreements within intermediary institutions (i.e. botanical gardens, gene banks) are often publicly available, those between the private sector and their suppliers are generally confidential. Thus, it is difficult to ascertain what best practices for MTAs entail, though Appendix I of the Bonn Guidelines does provide a list of possibilities for reference.

### **Monetary and Non-Monetary Benefits**

In the context of benefit sharing, the precise definitions of benefits require further explanation. While a notion of *monetary* benefits may be reasonably intuitive to most (i.e. a transfer of financial resources from the party acquiring the resource to the community or country originally holding the resource), *non-monetary* benefits are not as intuitive to grasp. Broadly speaking, this latter form of benefits refers to a transfer of some element of strategic use to the original holder (or representative of) from the acquiring party. Consider this; a patent is granted to a private, foreign owned firm on an invention that is based on, for example, medicinal knowledge over a herb used by generations of an indigenous community. One example of a non-monetary benefit could be that conditional on the patented knowledge being transferred, the production of the pharmaceutical that results out of the medicinal herb (assuming it successfully passes clinical trials and is marketed) must take place within the borders of the country that originally held the material. The rationale for this is to facilitate skill building in the production of pharmaceuticals, with the hope that these skills can be applied domestically to foster economic growth in the holder country. Such an arrangement is referred to as “working” a patent; this can be applied to a wide variety of resources. Where the benefits in this example did not involve an explicit transfer of funds based on a valuation of the resource, the benefits accrued by the holding country are certainly not intangible.

### **Bilateral and Multilateral Agreements**

In Article 15, the CBD sets up a framework of general principles for structuring the international exchange of genetic resources premised upon the national sovereignty of each country over genetic resources within its jurisdiction and with the objective of facilitating access to genetic resources. The Article in keeping with the orientation of the treaty generally, focuses on national action and through reference to mutually agreed terms and prior informed consent. This implies a negotiation – a bilateral approach – between source countries and recipients for access to genetic resources. It does not, however, preclude a multilateral approach or system should the parties choose to adopt such a system for all genetic resources or some subset of these.

The FAO’s ITPGR, which is primarily based on CBD-principles, however provides for a Multilateral System of Facilitated Access and Benefit Sharing, thereby obliging countries to forego the possibility of bilateral arrangements. This being the case, the benefits resulting from their use, including commercial use, do not return to the country of origin, but are to be shared in a fair and equitable manner through multilateral mechanisms.

#### Box 4: The Kani Experiment - An Indian Experience in ABS

Dr. P. Pushpangadan, Director, National Botanical Research Institute has developed a successful model of equitable benefit sharing which relates to a unique and successful experiment on a sustainable lesser-known wild plant and the subsequent development of an equitable sharing of benefits between a research organization and a semi-nomadic forest dwelling tribe, the 'Kanis'.

The genesis of the programme dates back to 1987 when Dr. Pushpangadan was functioning as the Principal Investigator (PI) and chief coordinator of an All India Coordinated Research Project on Ethnobiology (AICRPE) sponsored by Ministry of Environment and Forests, Government of India. In one of the field expeditions in 1987 in the mountainous forests of Western Ghats of Kerala, Dr. Pushpangadan was accompanied by a few young Kani men. During the arduous trekking, Pushpangadan observed that the Kanis ate some fruits, which kept them energetic and agile. Dr. Pushpangadan and the accompanying scientists were also offered these fruits by those Kani men. Dr. Pushpangadan consumed them and within 15 minutes, he felt a 'sudden flush of energy and strength'.

The Kani men were, however, reluctant to reveal their secret about the knowledge and the resources. Dr. Pushpangadan assured them that they will not misuse the information and the plant would be scientifically investigated and if found promising, a drug based on it would be developed for the welfare of humanity. He also assured that when such products were commercialized, he would ensure equal sharing of benefits to them. After great persuasion, the Kanis finally showed him the plant, later identified as *Trichopus zeylanicus*, which the Kanis called *Arogyapacha* meaning evergreen health.

Dr. Pushpangadan carried out scientific investigations (phytochemical and ethnopharmacological) on the plant. The study revealed that the plant contained various glycolipids and non-steroidal compounds with profound adaptogenic and immunoenhancing properties. After seven years of intensive scientific research, a scientifically verified and standardized herbal formulation 'Jeevani' was developed. In 1996, Dr. Pushpangadan transferred the production technology of 'Jeevani' to the Arya Vaidya Pharmacy (AVP), Coimbatore against a licence fee of US \$ 50,000 and a royalty of two percent at ex-factory sale rate. While transferring the technology Tropical Botanical Garden and Research Institute (TBGRI), Thiruanantapuram (where Dr. Pushpangadan joined as a director in 1990) agreed to share the licence fee and royalty received from AVP with the Kanis on 1:1 ratio.

However, it took almost two years to transfer the benefits to the 'Kani' tribe. The 'Kani' tribe is an unorganized forest dwelling semi-nomadic tribe. Dr Pushpangadan and his colleagues with the help of some NGOs motivated the tribe to organize themselves. Subsequently they constituted a trust known as the 'Kerala Kani Samudaya Kshema Trust'. In March 1999, TBGRI transferred an amount of Rs. 650,000 to the Trust, which decided to keep the capital amount in a fixed bank deposit and to utilize only the accrued interest of the amount for various community development programmes.

The benefit sharing model evolved and experimented by Dr. Pushpangdan and his team has received wide acclaim, acceptance and popularity as it was the first of its kind in the world to recognize and reward the IPR of an indigenous community for sharing their indigenous knowledge that resulted ultimately in the development and commercialisation of a useful value added product. It was an innovative model because it implemented the Article 8(j) of CBD, both in letter and spirit. It is, however, interesting that the modalities of this benefit sharing exercise had begun in 1989, much before the CBD came into being. The model now benefits over 16,000 Kani people comprising of over seven hundred families.

SOURCE: Source: Based on Dr. Pushpangadan's presentation at the meeting held in Delhi on 7 July 2004 titled "Protection of Indigenous Knowledge of Biodiversity; and the work that qualified the Equator Initiative Award to Dr. P. Pushpangadan, [www.undp.org](http://www.undp.org)

## WHAT HAVE COUNTRIES DONE TO IMPLEMENT THE BONN GUIDELINES?

There are a number of countries that have implemented legislation to incorporate the Bonn Guidelines into legal frameworks that address ABS issues. For our purposes, we confine our analysis primarily to those countries found between the tropics, given that it is these countries that are richest in biodiversity, and those countries that make explicit mention of PGR in their respective policies<sup>5</sup>.

In order to facilitate our analysis, we have countries next to whether or not they have incorporated the key provisions we have discussed here, and if so, what the corresponding article/section is within the legislation (Table 2). The date of the legislation or draft is provided; those pieces of legislation delineated by an asterisk (\*) are currently in force.

Table 2: ABS in legislation

Country or Region	Legislation	MAT	PIC	MTA
Andean Community	Andean Community Decision 391: Common Regime on Access to Genetic Resources (02.07.96) <sup>6*</sup>	42 <sup>7</sup>		9 <sup>8</sup> ,17i <sup>9</sup>
ASEAN	The ASEAN Framework Agreement on Access To Biological and Genetic Resources (24.02.00)	11 <sup>10</sup>	2, 8, 10 <sup>11</sup>	11
Bangladesh	Biodiversity and Community Protection Act of Bangladesh (29.09.98)	13.9, 13.20 <sup>12</sup>	2d, 7, 13.3, 13.4 <sup>13</sup>	16.5, 16.6 <sup>14</sup>
Bolivia	Supreme Decree No. 24676, Regulation of Decision 391 on the Common Regime for Access to Genetic Resources (21.06.97)*	18, 37, 41 <sup>15</sup>		
Brazil	Provisional Measure No. 2.186-16 (23.08.01)*	19, Ch. 7 <sup>16</sup>	11 <sup>17</sup>	14 <sup>18</sup>
Costa Rica	The Biodiversity Law No. 7788 (30.04.98)*	63 <sup>19</sup>	63, 65 <sup>20</sup>	76 <sup>21</sup>
India	Biological Diversity Act (11.12.02)*	21.1 <sup>22</sup>	Ch. 2, 5, 6 <sup>23</sup>	21.4, Ch. 7, 8 <sup>24</sup>
African Union	African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (2000)	8.1 <sup>25</sup>	18, 60 <sup>26</sup>	11.3 12.2 <sup>27</sup>
Pakistan	Legislation on Access to Biological Resources and Community Rights (Draft, No Date Given)	4.2 <sup>28</sup>	4.2, 4.4, 5.3, 6.3(b) <sup>29</sup>	4.3 <sup>30</sup>
Peru	Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources (10.08.02)*	27 <sup>31</sup>	6, 42 <sup>32</sup>	7, 8, 27(c) <sup>33</sup>
Philippines	Department of Environment and Natural Resources Administrative Order 96-20 (09.07.96) <sup>34*</sup>	8.1 <sup>35</sup>	6.1.3,7 <sup>36</sup>	8.1.14 <sup>37</sup>

Clearly, there exists asymmetries regarding how individual countries have implemented the Bonn Guidelines; the definitions of PIC and MAT differ among countries. While some countries require PIC directly from the holders themselves (i.e. Philippines, Costa Rica, Brazil), others only require PIC from the state (i.e. ASEAN, India). Similarly,



while some provide explicit guidelines for both MAT and MTA, others do not, and one assumes that these would be formulated on an *ad hoc* basis using, for MTAs, Appendix I of the Bonn Guidelines as best practices. More details can be found on the particular implications of the relevant articles below.

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<sup>1</sup> Genetic resources are defined by Article 2 of the CBD to include genetic material of plant, animal, microbial or other origin containing functional units of heredity.

<sup>2</sup> See Newman, D.J. and S.A. Laird (1999). "The Influence of Natural Products on 1997 Pharmaceutical Sales Figures." The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit Sharing. Ed. K ten Kate and S A Laird. London: Earthscan.

<sup>3</sup> See Myers, N., et al (2000). "Biodiversity Hotspots For Conservation Priorities." Nature. 403. 853.

<sup>4</sup> Correa, C. M. and Musungu, S. F., WIPO Patent Agenda: Risks for Developing countries, South Center, 2002

<sup>5</sup> GRAIN maintains a list of countries and provides links to the ABS legislation each country has developed; this can be found at <http://www.grain.org/brl/abs-brl-en.cfm>. Similarly, the International Environmental Law Project maintains a similar resource; look to <http://www.lclark.edu/org/ielp/genetic.html>. Finally, Dr. Peter-Tobias Stoll at the University of Gottingen maintains a similar database; it can be found at <http://wwwuser.gwdg.de/~ujvr/wirtschaft/forschung/access.htm>.

<sup>6</sup> Decision 391 applies to the five members of the Andean Community; namely, Bolivia, Colombia, Ecuador, Peru, and Venezuela. We consider Bolivia and Peru in more detail here as well as there are other provisions (i.e. PIC) which are not explicitly stated in Decision 391.

<sup>7</sup> Article 42 deals with ancillary contracts, which are defined as "those that are signed in order to carry out activities connected with the genetic resource or its by-products"; in this context, the article states that upon the signing of any access contract are governed by MAT, among other stipulations.

<sup>8</sup> Technology transfer is explicitly stated as a requirement in Article 9.

<sup>9</sup> Article 17 broadly outlines a number of conditions that "...applications for access and access contracts and, if appropriate, accessory contracts" within the context of ABS should include; section (i) explicitly deals with the terms of transfer for "material to which third parties are given access."

<sup>10</sup> Article 11 deals with the "Fair and Equitable Sharing of Benefits", which details the minimum set of requirements for exchange to occur. These terms explicitly cover MAT and MTAs.

<sup>11</sup> While Articles 2 (the objectives) and 8 (establishing national authorities) incorporate PIC into their aims, Article 10 deals with PIC explicitly and lays out what information must be made mutually available with regards to PIC.

<sup>12</sup> Article 13.9 explicitly describes what the requirements and conditions for access are, thus providing a template for MAT; similarly, 13.20 establishes the state as being responsible for ensuring that these requirements are adhered to.

<sup>13</sup> Article 2 lays out the objectives of the act, and in doing so makes mention in part (d) about how all processes relating to access must include PIC. Article 7 is entirely devoted to PIC and also provides a list of requirements for communities to assert their ownership over these resources. Similarly, Article 13 provides the general provisions for access, and 13.3 and 13.4 establishes PIC as a necessary condition for access.

<sup>14</sup> Article 16 details the requirements for commercial access; it states in 16.5 and 16.6 that fees are payable to the state for access (to be determined presumably on an *ad hoc* basis) and that 50% of any profit derived from access and successful commercialisation will be directed towards the community (ies) of origin.

<sup>15</sup> Article 18 specifies what a request for access must include; the stipulations outlined here are in addition to those outlined Article 42 of the Andean Decision. Similarly, Article 37 outlines additional clauses to be included in any contract of access; these conform with the analog conditions in the Andean Decision 391. Finally, Article 41 details the benefits derived from access (i.e. technology transfer, tax exemptions, etc).

<sup>16</sup> While Article 19 addresses the conditions by which transfer will be governed by with regards to exchange between two parties, chapter 7 in its entirety is concerned with benefit sharing issues; Article 25 defines potential monetary and non-monetary benefits.

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<sup>17</sup> Article 11 establishes the role of the Management Council (i.e. the body that will enforce the provisional measure) as, among other things, to ensure that access and/or the collection of samples only occurs with the PIC of the owner.

<sup>18</sup> Article 14 further establishes what the Council is capable of doing in terms of creating ancillary bodies to address ABS concerns; among other tasks, 14.4 states that a “national public research and development institution or Federal public management institution” could be mandated by the Council to “take part in the implementation of Terms of Transfer of Material and Contracts for the Use of the Genetic Heritage and Benefit-Sharing”. However, the Brazilian model does not explicitly lay out what the MTA should consist of in terms of salient features.

<sup>19</sup> Article 63 lays out the basic requirements for access and states that “[t]he terms of technology transfer and equitable distribution of benefits, when they exist, agreed to in the permissions, agreements and concessions, as well as the type of protection of the associated knowledge that demands the representatives of the place where access occurs” is a necessary condition for access.

<sup>20</sup> Article 63 states PIC as one of the basic requirements for access. The article also states who is responsible for endorsing the request, namely the Technical Office of the Commission. Article 65 is entirely devoted to PIC, and establishes the requirement for interested parties to either acquire PIC from the “landowner where they develop the activity, or with the authority of the indigenous community when the activity is in the indigenous territories and the Director of the Conservation Area.”

<sup>21</sup> Article 76, the General Rules for Access, state that “the interested party must deposit up to ten percent (10%) of the research costs and up to fifty percent (50%) of the royalties collected in favor of the National System of Areas of Conservation, the indigenous territory or the private proprietor that provides access to components; in addition, it will be determined the amount that in each case the interested parties must pay in expenses of proceedings, as well as any other benefit or technology transfer that comprises of the prior informed consent.”

<sup>22</sup> Article 21, the Determination of Equitable Benefit Sharing by National Biodiversity Authority, explicitly mentions MAT in subsection (1). Similarly, subsection (2) presents six distinct components of any ABS agreement (though not all are required to be met for access).

<sup>23</sup> PIC in the Indian legislation is somewhat unique in comparison to the other mechanisms included in this overview. Nowhere in the legislation itself is PIC referred to; rather prior *intimation* is required. Moreover, this arguable analogue of PIC is not necessarily required of the holders themselves, but more of the National and State Biodiversity Boards. No explicit links are provided between the State and the holders, and it leads one to believe that the decision lays ultimately in the hands of state rather than the holders themselves. One could argue that this does not technically constitute PIC at all (as per the definition presented here); indeed, in an intuitive sense, PIC would seem to be required from the holders of the resource rather than anyone else.

<sup>24</sup> MTAs in the Indian context are also somewhat unique; the Indian legislation has set up a National Biodiversity Fund, which exists to “channel benefits to the benefit claimers”. However, the legislation does not state what is required to be the precise elements of the MTA. That said, Article 21.4 states that the “...National Biodiversity Authority shall, in consultation with the Central Government, by regulations, frame guidelines” for these purposes.

<sup>25</sup> Article 8.1 lays out what the contents of any agreement on access must include.

<sup>26</sup> Article 18 states that access is conditional on the PIC of “...the concerned community or communities ensuring that women fully and equally participate in decision making”. Article 60 links the enforcement of this with the National Inter-Sectoral Coordination Body.

<sup>27</sup> Article 11.3 states that no transfer will occur until “...an [MTA] reserving the prior rights of the state and/or communities or community.” However, no criteria for what an MTA should include in its’ provisions is provided within the model law. That said, Article 12.2 on Benefit Sharing states that “the State and the community or communities shall be entitled to a share of the earning derived from when any biological resource and/or knowledge collected generates, directly or indirectly, a product used in the production process.”

<sup>28</sup> Article 4 relates explicitly to Access to Biological Resources and Related Community Knowledge and Technologies. 4.2 details the MAT for access.

<sup>29</sup> In Article 4.2 and 4.4, PIC is expressed in two contexts, first as an overwhelming condition for access, and second as a condition for export and, interestingly, import. Article 5 relates to Community Rights, and expresses PIC from the Community that holds the resources as a necessary condition. Finally, Article 6

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details the roles and responsibilities of the National Inter-sectoral Coordination Body, of which enforcing PIC is one.

<sup>30</sup> Article 4.3 states the minimum requirements for any agreement on access; subsection (e) provides for a “...provision for the payment of [loyalties] [a fixed sum of money] to the national government or local communities, in case commercial use is derived from the biological resources taken.”

<sup>31</sup> Article 27 details what a license contract for access must include; there are 6.

<sup>32</sup> Article 6 outlines the conditions to access; it states that “[t]hose interested in having access to collective knowledge for the purposes of scientific, commercial and industrial application shall apply for the prior informed consent of the representative organizations of the indigenous peoples possessing collective knowledge.” Similarly, Article 42 details the rights of indigenous peoples possessing collective knowledge; its states that “[i]ndigenous peoples possessing collective knowledge shall be protected against the disclosure, acquisition or use of that collective knowledge without their consent and in an improper manner provided that the collective knowledge is not in the public domain.”

<sup>33</sup> Article 7 details the conditions for access among those who have commercial interests. It states that “...a license agreement shall be signed in which terms are provided that ensure due reward for the said access”. Similarly, Article 8 states that “[a] percentage which shall not be less than ten per cent of the value, before tax, of the gross sales resulting from the marketing of goods developed on the basis of collective knowledge shall be set aside for the Fund of the Development of Indigenous Peoples”. This fund, “created for the purpose of contributing to the comprehensive development of indigenous peoples through the financing of projects and other activities”, is described in more detail in Article 37. Finally, among the MAT that Article 27 presents, subsection (c) requires “[a] statement of the compensation that the indigenous peoples receive for the use of their collective knowledge; such compensation shall include an initial monetary or other equivalent payment for its sustainable development, and a percentage of not less than five per cent of the value, before tax, of the gross sales resulting from the marketing of the goods developed directly and indirectly on the basis of the said collective knowledge, as the case may be”.

<sup>34</sup> This order operationalizes Executive Order No. 247, "Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-Products and Derivatives. For Scientific and Commercial Purposes, and for Other Purposes". Where EO 247 lays out the objectives, 96-20 provides explicit guidelines.

<sup>35</sup> Section 8 is entirely devoted to the minimum terms and conditions of a research and academic agreement.

<sup>36</sup> Article 6.1.3 states that PIC must be acquired from one or more of these parties depending on the situation; Indigenous Peoples (if the resource is held on ancestral lands), Local Communities, Protected Area Management Board, or a Private Landowner. Article 7 then describes in detail how to acquire PIC from the relevant parties.

<sup>37</sup> Article 8.1.14 states “[a] separate agreement shall be made for the transfer of royalty, benefits, technology and agreements”. Again, Section 8 in its entirety provides the minimum guidelines for a research agreement, and is quite detailed.



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