THE ABS CAPACITY DEVELOPMENT INITIATIVE

L'INITIATIVE DE RENFORCEMENT DES CAPACITES POUR L'APA

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The ABS Capacity Development Initiative, in collaboration with the Governments of Brazil, India and South Africa, commissioned national studies to review each country's experiences with Access and Benefit Sharing. Lessons learned from these experiences will inform the global implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from its Utilization (Nagoya Protocol). These studies were prepared to provide background information in preparation for the first Dialogue on Practical Ways Forward for the Implementation of the Nagoya Protocol, hosted by the Government of South Africa on 30-31 January 2014 in Cape Town, South Africa and the second Dialogue on the same topic, co-organized with the Ministry of Environment and Forests of India, from 4-6 August 2014 in Goa, India.

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Background

Brazil ratified the CBD in 1994 and has always attached great importance to its third objective. During the 1990s a number of draft ABS bills were submitted to the National Congress by parliamentarians. ABS laws were enacted by two states in the Amazon region. An inter-ministerial committee on ABS began work in 1996 and in 1998 the federal government submitted its draft bill to Congress.

However these procedures were short-circuited in 2000 with the eruption of protests over the signing of a spurious bio-prospecting arrangement between a publicly-funded Brazilian non-governmental institution and a multinational pharmaceutical company. The contract was denounced as an act of biopiracy and the government was forced to enact provisional legislation to regulate the juridical vacuum. An initial Provisional Act was issued in June 2000. This act was revised and re-issued a number of times. The current version (Provisional Act 2.186-16) entered into force in August 2001. Subsequently the legislation on the validity of provisional legislation was changed and Provisional Act 2.186-16 has become the de facto national ABS law.

There have been repeated attempts to arrive at agreement on a draft of a definitive ABS law for submission to Congress, but agreement within the federal government has proved elusive. Following the adoption of the Nagoya Protocol a fresh attempt to agree a consensus draft has been taking place within the federal government, together with submission of the Protocol for approval by Congress and subsequent ratification.

National framework

Who are the competent national authorities?

Brazil has not yet notified the CBD Secretariat of the designation of the Competent National Authority as provided for in Article 13, paragraph 4 of the Nagoya Protocol. However under the Provisional Act and its supporting legislation the body with the responsibilities listed in Article 13, paragraph 2 of the Nagoya Protocol is the Genetic Heritage Management Council (*Conselho de Gestão do Patrimônio Genético - CGEN*).

The Environment Unit of the Ministry of External Relations is the National Focal Point for the Intergovernmental Committee for the Nagoya Protocol (NFP ICNP ABS).

The CGEN was created by the Provisional Act and its composition, mandate and rules of procedure were defined in Presidential Decree 3.945 of 28 September 2001.

The CGEN is administered by the Ministry of the Environment, which presides the council. Eighteen further federal bodies are voting members. The Genetic Heritage Department of the Secretariat of Biodiversity and Forests of the Ministry of the Environment is the secretariat of the CGEN. The Ministry of the Environment has extended permanent observer status on the CGEN to organizations representing indigenous and traditional communities, NGOs, state-level environment agencies, the scientific community, the office of the federal prosecutor-general and business federations.[1]
Under the Brazilian ABS framework the term employed is 'genetic heritage' (*patrimônio genético*) consistent with Article 225 of the 1988 Federal Constitution, rather than the term 'genetic resources' as used in the CBD.

What is the scope of the measures in place?

The Federal Constitution requires the state to 'preserve the diversity and integrity of the genetic heritage of the country and to oversee bodies engaged in research on and manipulation of genetic material' (*Art.225, 1º, II*).

Brazil has ratified the CBD, ILO Convention 169 and ITPGRFA (1994, 2002 and 2006 respectively) and these have been incorporated into national law. It has signed the UN Declaration on the Rights of Indigenous Peoples.

Provisional Act 2.186-16 enacts Articles 1, 8j, 10c, 15, 16.3 and 16.4 of the CBD by regulating:

(i) access to components of genetic heritage existing within the national territory, on the continental shelf and in the exclusive economic zone, for the purposes of scientific research, technological development or bioprospecting;

[1] See Annex 1

(ii) access to traditional knowledge associated to genetic heritage, related to the conservation of biological diversity, to the integrity of the country's genetic heritage and to the use of its components;
(iii) the fair and equitable benefits arising from the use of components of genetic heritage and associated traditional knowledge;
(iv) access to and transfer of technology for the conservation and sustainable use of biological diversity (*Art.1*).

"Access" is not the same as "collection" (see below). The three categories of access activity covered by the Provisional Act are scientific research, technological development and bioprospecting. These are defined as follows:

Scientific research: research conducted on samples of genetic heritage for non-commercial purposes.

Some types of research and scientific activity may in principle involve access to genetic heritage for scientific research because they employ molecular methodological tools and not because their objectives involve access. However the purpose of the Provisional Act is to ensure the fair and equitable sharing of benefits and thus scientific research that does not contemplate the generation of possible benefits is exempt from the authorization requirements. The CGEN has clarified that the following activities are exempt:

- research intended to evaluate or elucidate the evolutionary history of a species or taxonomic group, relationships of living beings to each other or to the environment, or the genetic diversity of populations;
- affiliation tests, sexing techniques and karyotype or DNA analysis aimed at the identification of a species or specimen;
- epidemiological research or research aimed at identification of the etiological agents of disease, together with measurement of the concentration of known substances whose quantities in an organism are indicators of disease or physiological state;
- research aimed at forming collections of DNA, tissue, germplasm, blood or serum (*CGEN Resolution 21*).

Technological development: systematic activity on the basis of existing knowledge aimed at the production of specific innovations or the development or modification of existing products and processes for economic gain (*CGEN Technical Guidance Note no. 4*).

Bioprospecting: exploratory activity aimed at identifying components of genetic heritage and/or information concerning associated traditional knowledge with potential for commercial use (*Provisional Act, Art.7*)

Under Brazilian legislation applicants for a patent on an invention developed from access to a component of Brazilian genetic heritage after 30 June 2000 are required to inform the patent office (*Instituto Nacional de Propriedade Industrial* – INPI) of the origin of the genetic material and/or associated traditional knowledge and the identification of the access authorization issued by the CGEN or other accredited authorizing body (*CGEN Resolution 34* and *INPI Resolution 207*).

Who owns genetic resources in your country? Who owns biological resources?

Biological resources are considered collective goods. Ownership of genetic resources is not specifically attributed in law, but the Provisional Act acknowledges that the owner of the land on which a genetic resource is collected has rights over the resource.

The Federal Constitution states that the environment is a common good and establishes the collective right to an ecologically balanced environment. It is the responsibility of the State and the population to protect and preserve this for present and future generations (*Art. 225*). Biological resources are held to be a component of the environment, and are thus collective goods.

To fulfil its responsibility to maintain an ecologically balanced environment, as previously noted the State is required, inter alia, to preserve the diversity and integrity of Brazil's genetic heritage and to oversee bodies engaged in research on and manipulation of genetic material. The responsibility for the management of genetic resources thus falls to the State.

However the Provisional Act acknowledges that rights over genetic resources are vested in the owners of the property where collection occurs. It states that, while access to components of genetic heritage must occur in conformity with the Provisional Act, this is "without prejudice to the material and immaterial property rights over the component of genetic heritage that is the object of the access or over the place where this occurs" (*Art. 1º, II, § 1º*). By acknowledging such property rights, the Provisional Act constitutes *de facto* confirmation of ownership.

This is further confirmed when the Provisional Act establishes the requirement for a contract (CURB *Contrato de Utilização do Patrimônio Genético e de Repartição de Benefícios* - Utilization of Genetic Heritage and Benefit Sharing Contract) between the parties whenever commercial application is envisaged or traditional knowledge is involved. When the collection occurs in a protected area the federal government is the party to the contract, in the person of the president of the CGEN. In other cases the beneficiary of the benefit sharing agreement, is "the owner of the public or private area, or the representative of the indigenous community and the official indigenous agency, or the representative of the local community" (*Art. 27*).

Is access to genetic resources or utilization of genetic resources defined? What activities are covered by ABS requirements?

Access to genetic heritage is defined as the obtaining of a sample of a component of genetic heritage for the purposes of scientific research, technological development or bioprospecting, with a view to industrial or another type of application (*Provisional Act, Art.7*).

Access activities that require federal authorization are those which:

(i) use any type of genetic material, whether of Brazilian animal, microbial, fungal or plant origin or domesticated exotic material which has developed characteristic properties;
(ii) use the traditional knowledge of indigenous or local communities associated with genetic material.

The CGEN has clarified that access is activity undertaken on genetic heritage that seeks to isolate, identify or use information of genetic origin or molecules and substances deriving from the metabolism of living beings and extracts obtained from such organisms (*CGEN Technical Guidance Note No. 1*).

Access is thus different from collection.

How is indigenous and local communities and traditional knowledge defined?

Indigenous community: an indigenous person is an individual of pre-Colombian origin and descent who self-identifies as such and is identified by others as belonging to an ethnic group whose cultural characteristics distinguishes it from the national society. An indigenous community or group is a group of indigenous families or communities that may be living in a state of complete isolation in relation to other sectors of national society or in intermittent or permanent contact, without however being integrated into these sectors (*Law N^{o} 6.001/1973 "Statute of the Indian"*).

There are 239 different indigenous peoples in Brazil, speaking 150 languages and occupying 689 *Terras Indígenas.* There are around 30 known 'isolated' indigenous groups (i.e. in a situation of voluntary isolation from surrounding indigenous or non-indigenous communities).

Local community: a human group, including descendants of *quilombola* [maroon] communities, distinguished by its cultural status, that has been traditionally organized over successive generations, has its own customs, and conserves its social and economic institutions (*Provisional Act 2.186-16*).

This definition has been refined by the 2007 *Decree Establishing the National Policy for the Sustainable Development of Traditional Peoples and Communities* which refers to 'traditional peoples and communities' rather than local communities and defines these as 'culturally differentiated groups that recognize themselves as such, that enjoy their own forms of social organization, that occupy and use territories and natural resources as the necessary basis for their cultural, social, religious, ancestral and economic reproduction, using knowledge, innovations and practices generated and transmitted by traditional means' (*Decree 6.040*).

There are multiple categories of 'traditional peoples and communities' to be found in different biomes, of various ethnic backgrounds and using different combinations of biological resources as the basis for their subsistence. They include, for example, *caiçaras* (traditional fishing communities on the Atlantic coast), *caboclos* (Amazon riverbank communities of mixed indigenous and Portuguese descent), *quilombolas* (communities, generally African-Brazilian, descended from settlements of escaped slaves), *seringueiros* and other *extrativistas* (rubber-tappers and other collectors of wild products), *pomeranos* (isolated communities descended from immigrants from the Baltic in the mountains of southeast Brazil), *povos faxinalenses* (communities of Ukrainian origin in southern Brazil with mixed collective and individual land use practices of pre-industrial eastern European origin), *povos de cultura cigana* (Roma communities), *quebradeiras de coco-de-babaçu* (rural women's groups with subsistence activities based on collecting and shelling nuts of the babassu palm), *comunidades de fundo de pasto* (rural communities of sheep and goat herders in the semi-arid region with a mixture of

communal and individual land use practices), *vazanteiros* (communities planting seasonal crops on the floodplains of rivers in the semi-arid and savannah biomes), and many more.

Associated traditional knowledge is defined as individual or collective information or practices of an indigenous community or a traditional community of actual or potential value associated with genetic heritage (*Provisional Act 2.186-16, Art.7*).

Who owns traditional knowledge? How is traditional knowledge found in the public domain (e.g. publications) addressed?

Traditional knowledge (TK) associated to the conservation and sustainable use of biodiversity and genetic resources is the property of the community that holds the knowledge. In the case of indigenous communities this is implicitly recognised in the chapeau to Article 231 ('On Indians') of the 1988 Federal Constitution which states:

> "Indians' rights are acknowledged to their social organization, customs, languages, beliefs and traditions and their prior rights to the lands they have traditionally occupied; it is the task of the Union to demarcate these and to protect and ensure respect for all their assets."

Indigenous community ownership of its traditional knowledge is acknowledged in the Provisional Act and similar entitlement is acknowledged for local communities:

> "Under this Provisional Act the traditional knowledge of indigenous communities and local communities associated with genetic heritage is protected against illicit use and exploitation and other prejudicial actions or actions not authorized by the CGEN [...]
>
> 1. The State acknowledges the right of indigenous communities and local communities to decide on the use of their traditional knowledge associated to the genetic heritage of Brazil […]
> 2. Traditional knowledge associated with the genetic heritage that is the subject of this Provisional Act forms part of the cultural heritage of Brazil […]
>
> The indigenous community and the local community that creates, develops, holds or conserves traditional knowledge associated to genetic heritage is guaranteed the right to:
>
> 1. Require the indication of the origin of the access to the traditional knowledge in all publications, usages, exploitations and dissemination;
> 2. Prevent unauthorized third parties from:
>   a. Using or undertaking tests, research or exploration related to the traditional knowledge;
>   b. Divulging, transmitting or retransmitting data or information that make up or constitute associated traditional knowledge;
> 3. Receive benefits from the economic exploitation by third parties, directly or indirectly, of the associated traditional knowledge whose rights they own in accordance with the provisions of this Provisional Act.
>
> Provision: for the purposes of this Provisional Act rights in respect of any traditional knowledge associated to genetic heritage may be considered as held by the community

notwithstanding cases where a single individual member of the community holds such knowledge" (*Provisional Act, Arts. 8 & 9*).

Thus TK is always collective, even in cases where it is held by a single member of the community – a legal precaution to forestall the possibility of an individual monopoly. Not all TK is covered, only that which holds actual or potential value and which is associated with the utilization of genetic resources.

The issue of how to address TK that has already in the public domain is complicated. As a megadiverse country, both biologically and culturally, Brazil has been intensely studied for more than three centuries – European and Brazilian 'naturalists' in the eighteenth and nineteenth centuries and legions of ethnologists, botanists, zoologists, medical researchers, agronomists, forest scientists, geneticists, ecologists and other disciplines in the twentieth and twenty-first centuries. These disciplines have been recently joined by researchers in gastronomy and perfumery.

The output is substantial – both published in the form of books, articles and theses, and recorded as television documentaries, videos and photographic records.

In accordance with Article 9 of the Provisional Act (see above) all research and recording involving TK associated to genetic resources since 2001 should have obtained the prior consent of the holders and, if placed in the public domain, should acknowledge the source of the knowledge. This question has been discussed by the CGEN, and although no formal deliberation has been made, it has recommended that researchers respect the intention of the legislation. Further discussion with a view to agreeing binding procedures will start shortly in the CGEN thematic working group on associated traditional knowledge.

What types of measures were adopted and implemented: Policy, legislation, regulations?

- One Provisional Act (*Medida Provisória 2.186-16, 23 August 2001)*
- Three Decrees (on the composition and operations of the CGEN (*Decreto 3.945, 28 September 2001*), on penalties applicable in cases of infringements of ABS rules (*Decreto 5.459, 7 June 2005*), and on distribution of shared profits and royalties when the Union is a party to an ABS contract (*Decreto 6.915, 29 July 2009*))
- Forty one CGEN Resolutions
- Nine Technical Orientation Notes
- 876 Access Authorizations approved by the CGEN and other accreditation bodies
- 192 Trustee Institutions accredited (comprising 358 separate *ex-situ* collections)
- Cross-references to four related legal instruments (laws on the protection of plant varieties, intellectual property, indigenous rights and the decree establishing the National Biodiversity Policy)
- Fifteen CGEN decisions on procedures [all figures as of December 2013].

How were national users of genetic resources considered (e.g. research institutes, universities)? Were they covered by the national measures? How?

The basis of the system is that access can only be authorized for national users. Applications for access to genetic resources and/or associated traditional knowledge can only be made by Brazilian institutions with legal personality. These may be public or private, commercial or academic. Applications need to be signed by the person with legal responsibility for the institution (i.e. in the case of a university, by the rector rather than the project director or faculty head, unless there has been a specific and legally valid delegation of responsibility for the purpose of the ABS application). Applications by individuals are not permitted; an individual researcher will need to be formally associated with and sponsored by a Brazilian institution. The application form requires identification of the members of the project team and links to their CVs in the national online database of researchers. Overseas institutional applicants are required to enter an association with a Brazilian institution, who will be the senior partner. The Brazilian partner will be responsible for submitting the application and will assume full legal responsibility. An individual overseas researcher will need to have a formal relationship with an overseas institution which has a partnership with a Brazilian institution.

All institutions, Brazilian and foreign, need to show (i) prior expertise in research and development in the field of biology, (ii) technical expertise to undertake the planned activities, and (iii) adequate infrastructure for handling genetic resources. The participation of foreign institutions in collecting and access requires approval by the CNPq (*Conselho Nacional de Desenvolvimento Científico e Tecnológico* - National Council for Scientific and Technological Development) in accordance with existing legislation and procedures on research in Brazil by foreign institutions. Foreign researchers will need to apply for the necessary temporary research visa at the Brazilian consulate in their home country.

Each applicant needs to identify a trustee institution accredited by the CGEN that will receive and house in a permanent collection voucher specimens of the genetic resources accessed. By December 2013 358 separate collections had been accredited.

What is the procedure for PIC?

The answers to the questions in this section should be understood in light of the distinction that, in the case of Brazil, needs to be made between PIC and access authorization. Prior consent is not the same as authorization to access. Prior consent of the provider needs to be obtained prior to application for the access authorization.

Under the Brazilian system the *anuência prévia* (prior consent) of the titleholder, community or body responsible for the area where genetic resources are to be collected is required for most categories of access authorization. Where such prior consent is required in order for the application for access to be considered, proof that the necessary consent has been obtained needs to be included with the application to the CGEN or other body accredited to decide on access applications.

An application for access that has been authorized and is in effect is not PIC in the sense used in some of the questions below.

An authorization for access includes authorization for shipment (*autorização de acesso e remessa*). The legislation makes a distinction between shipment (*remessa*) and transport (*transporte*) (*CGEN Technical Guidance Note No. 1*).

> Shipment: the despatch, permanent or temporary, of a sample of a component of genetic heritage for the purposes of access for scientific research, bioprospecting or technological development where responsibility for the sample is transferred from the sending institution to the receiving institution.
>
> Transport: the despatch of a sample of a component of genetic heritage for the purposes of access for scientific research, bioprospecting or technological development where responsibility for the sample is not transferred from the sending institution to the receiving institution.

Shipment requires signature of a material transfer agreement (*termo de transferência da material* – TTM) by both institutions that are bound by its specific conditions. Procedures have been established by the CGEN for shipments of samples of components of genetic heritage found *in situ* in the national territory, the continental shelf or the exclusive economic zone and maintained *ex situ* for the purposes of access for (i) scientific research with no potential economic utilization or (ii) bioprospecting (*Resolutions 20* and *25* respectively).

Transport of a sample of a component of genetic heritage requires signature of an agreement on responsibility for transport of material (*termo de responsabilidade para transporte de material* – TRTM) by the authorized institution and the researcher. In cases where the transport of a sample of a component of genetic heritage found *in situ* in the national territory, the continental shelf or the exclusive economic zone involves access solely for the purposes of carrying out scientific research with no potential economic utilization the deposit of a sample in a collection of the institution where the research is to be carried out is not required (*CGEN Resolution 15*).

Who may grant PIC for use of GR and TK?

[For "PIC" read "access authorization"] Before authorizing access to or shipment of components of genetic heritage or associated traditional knowledge, the CGEN or other accredited authorizing body requires evidence of prior approval of the provider as follows:

- the indigenous community involved, together with confirmation from FUNAI (the federal indigenous affairs agency), when access will involve a component of genetic heritage collected in a *Terra Indígena* or will involve associated traditional knowledge;
- the local community involved when access will involve a component of genetic heritage collected in its territory or will involve associated traditional knowledge;
- the responsible official body (i.e. at federal, state or municipal level) when access will involve a component of genetic heritage collected in a protected area;
- the landowner when access will involve a component of genetic heritage collected on private property;
- the National Defence Council when access will involve a component of genetic heritage collected in a national security area;
- the Navy when access will involve a component of genetic heritage collected in Brazilian jurisdictional waters, the continental shelf or its Exclusive Economic Zone;
- IBAMA (the federal environment agency) when access to a component of an endemic or endangered animal species is sought and in the case of CITES-listed species.
- Rio de Janeiro Botanical Garden (JBRJ) when access to a component of an endemic or endangered plant species is sought.

If the application will involve access to the traditional knowledge of indigenous or local communities for either scientific or commercial activity, the process of obtaining the prior approval of the community involved should follow the following guidelines:

- Make clear in language that is understandable to the community the purpose, methodology, duration and budget of the project; the intended use of the traditional knowledge sought; the geographic area of the activity and the communities involved;
- Respect the forms of social organization and of traditional political representation of the communities involved;
- Make clear to the community the expected social, cultural and environmental impacts to be caused by the project;
- Make clear to the community the rights and responsibilities of all the parties in the execution of the project and its outcomes;
- Establish in agreement with the community the modalities and forms of the benefit sharing;
- Ensure the right of the community to refuse access to its traditional knowledge is respected (CGEN Resolution 5, Article 2).

Since 2003 IBAMA has been accredited by the CGEN to issue authorizations for access to genetic heritage with no associated traditional knowledge involved for the purposes of scientific research. By December 2013 IBAMA had authorized 806 applications.

The National Council for Scientific and Technological Development (CNPq) is similarly accredited since 2009 to issue authorizations for access to genetic heritage with no associated traditional

knowledge involved for the purposes of scientific research, bioprospecting and/or technological development. By December 2013 the CNPq had authorized 224 applications.

The Institute for National Historical and Artistic Heritage (IPHAN) has been accredited since 2011 to issue authorizations for access to associated traditional knowledge without access to genetic heritage for the purposes of scientific research. By December 2013 IPHAN had authorized 27 applications.

The CGEN will assess all other applications that do not fall into one of the above categories. By December 2013 the number of such authorizations totalled 257.

In order to enable a series of research projects carried out by the same institution to benefit from a single application for access authorization, the institution can submit an application for special access and shipment authorization (*autorização especial de acesso e remessa*) which will enable a portfolio of projects to be undertaken under the terms of a single authorization for the period of its validity. Applications for special authorizations for scientific research are dealt with by IBAMA and for bioprospecting by the CGEN.

The CGEN is also responsible for approving special authorizations for access to genetic heritage for the purposes of constituting and adding to ex situ collections. Such authorization enables the establishment of ex situ collections that involves access activities such as DNA banks for their creation and that have the potential for economic utilization. This authorization does not permit the carrying out of any other activities involving access, which must be applied for separately through the relevant procedures.

What are the key conditions for obtaining PIC?

[For "PIC" read "access authorization"] The key conditions for approval by the CGEN and the other accredited bodies of authorization to access a component of genetic heritage and/or associated traditional knowledge comprise submission of:

- Proof of legal status of the institution and of the signatory;
- Proof of institutional standing and capacity:
    - Legally constituted under Brazilian law;
    - Prior experience of research and development in the field of biology;
    - Technical expertise to undertake the planned activities;
    - Adequate infrastructure for handling genetic resources;
- Identification of an accredited trustee institution that will hold in a permanent collection a voucher specimen of the genetic resources involved;
- A legal binding declaration on the part of the applicant institution that, if the access sought is for scientific research only, all activities will be restricted to this end;
- A research project specifying the intended use to which the genetic resources or TK will be put and containing:
    - Justification, objectives, methods and anticipated results;
    - Geographical location and time frame and, when TK will be accessed, identification of the indigenous or local community involved;
    - Identification of the type of material or information to be accessed and an approximate quantification of the samples to be collected;

    - Funding sources, with respective contributions and details of the responsibilities and rights of each of the parties;
    - Identification of team members and copies of any CVs not already publicly available on the national database of academic researchers;
    - In the case of institutional networks, copies of relevant legal documents such as contracts, cooperation agreements, memoranda of understanding;
- Proof of prior consent as outlined above. CGEN Resolutions have clarified prior consent requirements for: access to associated traditional knowledge for scientific research (*Resolution 5*); access to associated traditional knowledge with the potential for or intention of commercial use (*Resolution 6*); access to a component of genetic heritage found in indigenous lands, private lands, lands owned or occupied by local communities and in sustainable use conservation areas, for scientific research (*Resolution 9*); access to a component of genetic heritage found in indigenous lands, protected areas other than sustainable use conservation areas, private lands, national security areas, Brazilian territorial waters, the continental shelf and the exclusive economic zone for the purposes of bioprospecting or technological development (*Resolution 12*)

Is the procedure different when GR are accessed for basic research purposes or for commercialization purposes?

Bearing in mind the difference between collection and access, as previously noted (section on scope above) collection of genetic resources for scientific research where TK is not involved is not subject to the provisions of the ABS legislation. A separate set of procedures – the SISBio (*Sistema de Autorização e Informação em Biodiversidade* - Biodiversity Authorization and Information System, administered by the Chico Mendes Institute for Biodiversity Conservation (ICMBio), the federal protected area management authority) – exist to authorize collecting activities for scientific research and teaching purposes with no commercial, industrial, sporting or environmental impact assessment or licensing purposes in federal environmental protection areas and in subterranean caverns or involving threatened species.

By March 2012 there were 25,500 researchers registered in the system. In 2011 2,323 authorizations and 178 permanent licences were granted (an increase of 51% over 2010). It is an online system with a maximum 60 day period for authorization decisions.

Non-commercial scientific research with no TK involved outside the areas covered by SISBio (federal environmental protection areas and caverns) or that does not involve threatened species requires only permission from the landowner. In such cases SISBio offers a voluntary registration process which provides the researcher with documentation to confirm his or her bona fide credentials and may help avoid possible problems with environmental agency or police inspections.

The procedures for access for the purposes of technological development or bioprospecting, whether to genetic heritage, associated traditional knowledge or both, and for scientific research involving TK involve application to the CGEN for authorization (bearing in mind the exemptions established by Resolution 21 and listed on page 4 above).

Is a two phase approach is in place, providing PIC for research and requiring a new PIC for commercialisation? What is the trigger for the second phase? For example clinical trials, patenting?

[For "PIC" read "access authorization"] If a potential economic use is found for a product or process deriving from a component of genetic heritage or associated traditional knowledge, irrespective of whether it may be possible to claim intellectual property protection over the product or process or not, and where this possibility was not envisaged under the original access authorization, the institution that was authorized undertakes to inform the CGEN or the other body that granted the access authorization in order to put into effect a CURB (*Contrato de Utilização do Patrimônio Genético e de Repartição de Benefícios* - Utilization of Genetic Heritage and Benefit Sharing Contract) (*Provisional Act, Art.16, para.5*).

Are there different PIC requirements for different types of genetic resources (e.g. marine, forest)?

[For "PIC" read "access authorization"] Only as far as who grants consent is concerned (see 'who may grant PIC?' above), but not as a consequence of the type of biome or ecosystem in question.

What is the average delay in obtaining PIC from the time access is officially requested?

[For "PIC" read "access authorization"] The sequence is the other way round. In order to apply to the CGEN for access authorization for the purposes of technological development or bioprospecting or that involves traditional knowledge, the applicant institution has to provide evidence of the prior consent of the landowner, indigenous community, local community or public body responsible for the area where collection will occur (*Resolutions 5, 6, 9 and 12*, see above). Therefore the CGEN Secretariat will usually only become aware that consent has been sought and been granted once the application for access is submitted.

The average time taken by the CGEN to consider and decide upon applications for access depends to a large degree on the applicant. The scenario for the fastest authorization time would be where the applicant is able to submit at the outset all the documentation required by law and in the right format. In such cases the CGEN Secretariat may be able to include it on the agenda of the monthly CGEN meeting within two months. If it is approved at that meeting with no reservations or requests for further information, the process of preparing the report of the meeting, review of decisions by the legal office of the Ministry of the Environment, obtaining the minister's signature and publication in the *Diário Oficial da União* (the federal gazette) may be complete in two months. The best case scenario is thus from four to six months. However the majority of applications are likely to take a lot longer.

There is currently a working group examining the CGEN rules of procedure with a view to trying to reduce the average time necessary.

Is PIC awarded for a particular period of time?

[For "PIC" read "access authorization"] The duration of the authorization for access is decided on a case-by-case basis in accordance with the project timetable laid out in the application. The authorization is typically granted for a period of two to five years.

Is a permit issued when PIC is granted?

[For "PIC" read "access authorization"] The authorization is published in the *Diário Oficial da União*, a summary is published on the CGEN Secretariat website and written confirmation in triplicate is distributed as follows: one copy on the project file, a second to the applicant institution and the third to the project coordinator.

What is the procedure in place for the negotiation of MAT:

Are MAT a condition for obtaining PIC?

[For "PIC" read "access authorization"] When the access activities to be undertaken on a component of genetic heritage or associated traditional knowledge involve economic use (i.e. activities considered by the legislation as bioprospecting or technological development) a contract is required. This is the CURB.

Are key elements of MAT set out (content requirements)? Is a template for MAT available?

Where required the CURB needs to be included with the application for access. Three CGEN resolutions clarify the procedures for the preparation and analysis of the CURB in accordance with the nature of the application:

- When the application involves only private parties as provider and user and does not involve associated traditional knowledge or wild fauna (*Resolution 7*);
- When the application involves access to a component of genetic heritage or associated traditional knowledge held by an indigenous or local community (*Resolution 11*);
- When the Union is one of the parties to the CURB (*Resolution 27*).

All CURBs are required to contain the following basic information: (i) purpose, identification and quantity of samples, intended use; (ii) duration; (iii) form of fair and equitable sharing of benefits and, as appropriate, access to and transfer of technology; (iv) rights and responsibilities of the parties; (v) intellectual property rights; (vi) rescission; (vii) penalties; (viii) subject to the law of Brazil. When the Union is one of the parties the CURB will be subject to the provisions of the public law regime.

The terms of the contract will not take effect until approved by the CGEN. All parties involved, providers and users, must be identified together with their credentials. In the case of the users, this includes the Brazilian applicant for access authorization and any institution, Brazilian or foreign, that will hold the samples following transportation or shipment.

The CURB needs to be consistent with the terms of the prior consent agreement, in particular as regards benefit sharing and access to and transfer of technology. The information on the identification of the genetic resources, the quantity of samples and the intended use needs to be accurate and precise. This should include the planned timetable for the stages of the research – collection, bioprospecting, product or process development, and marketing, as appropriate.

Are specific requirements in place for the sharing of monetary and non-monetary benefits?

The Provisional Act provides for five possible categories of benefits: (i) profit-sharing; (ii) payment of royalties; (iii) access to and transfer of technology; (iv) free licensing of products and processes; (v) capacity building of human resources (*Art. 25*).

Benefits in the form of profit-sharing and royalties when the Union is the beneficiary (and fines levied for non-compliance with the ABS legislation) are to be allocated as follows (*Decree 6.915/2009*):

- When they result from access to a component of genetic heritage collected in an area belonging to the Union, but not located in territorial waters, the continental shelf or the exclusive economic zone:
    - Fifty per cent to the National Environment Fund (*Fundo Nacional do Meio Ambiente* – FNMA);
    - Fifty per cent to the National Scientific and Technological Development Fund (*Fundo Nacional de Desenvolvimento Científico e Tecnológico* – FNDCT);
- When they result from access to a component of genetic heritage collected in territorial waters, the continental shelf or the exclusive economic zone:
    - Twenty five percent to the National Environment Fund;
    - Twenty five per cent to the National Scientific and Technological Development Fund;
    - Fifty per cent to the Naval Fund (*Fundo Naval*).

When genetic resources are obtained from a private property the parties will establish the nature of the benefits to be shared directly with the provider.

A recent CGEN Resolution (no. 40, February 2013) establishes criteria for benefit sharing resulting from access to a component of genetic heritage for the purposes of commercial use obtained under the following circumstances:

- From a commercial enterprise where identification of the original provider is not possible;
- From an area belonging to the institution that undertakes the access;
- From an area whose owner renounces the right to benefits;
- From an *ex situ* collection held by the institution that undertakes the access where the sample was collected prior to publication of the first Provisional Act in June 2000.

In such cases the benefit-sharing arrangements to be proposed should preferentially contribute to the conservation and sustainable use of Brazilian biodiversity for the benefit of the nation, including to the restoration, creation and maintenance of *ex situ* collections; support to scientific research and to technological development linked to genetic resources; and building human resource capacity associated to the development of activities related to the use and conservation of genetic heritage.

What types of compliance measures are in place in order to ensure that users respect ABS requirements in your country?

Bearing in mind that the legally-responsible user will in all cases be a Brazilian institution, the Provisional Act requires all those who use or economically exploit components of genetic heritage or associated traditional knowledge to ensure that such activities conform to the provisions of the Provisional Act and subsequent instruments *(Article 34*). Article 30 of the Provisional Act establishes administrative sanctions for non-compliance. According to the gravity of the non-compliance, one of thirteen categories of punishment can be applied. These are: (i) warning, (ii) fine, (iii) seizure of samples and equipment, (iv) seizure of derived products, (v) suspension of the sale of derived products, (vi) suspension of activities, (vii) partial or total closure of the facility, activity or business, (viii) suspension of register, patent, licence or authorization, (ix) cancellation of register, patent, licence or authorization, (x) loss or reduction of government incentives or tax benefits, (xi) prohibition or suspension of access to official credit, (xii) intervention in the business, (xiii) five-year ban on participation in contracts or any other business dealings with public bodies

Who are relevant stakeholders at the national level (e.g. research community, universities, ex situ collections, indigenous and local communities, private land owners)?

All the above: universities and research institutions; ex situ collections, in particular the 192 institutions and their 358 collections accredited as trustees by December 2013; indigenous and local communities; business sectors that use genetic resources; protected area managers at federal, state and municipal levels; the 19 federal bodies that comprise the CGEN; the organizations with permanent observer status on the CGEN representing indigenous and traditional communities, NGOs, state-level environment agencies, the scientific community, the office of the federal prosecutor-general, and business federations.

What is the mechanism of implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)? What is its relationship with the ABS framework? How are the crops listed in Annex 1 of the ITPGRFA treated in the national ABS framework?

Access and shipment of samples of plant genetic resources of the species listed under Annex 1 of the ITPGRFA for the purposes of conservation, research, plant breeding and training in connection with food and agriculture, together with the sharing of benefits resulting from their utilization, are governed by the provisions of the Treaty.

The provisions of the Provisional Act 2.186-16 apply in the case of:

- Access to and shipment of other plant genetic resources obtained *in situ* in Brazil, and
- Access to and shipment of samples of plant genetic resources listed under Annex 1 of the Treaty for chemical, pharmaceutical and/or other industrial uses not related to food or animal feed (*CGEN Technical Orientation Note no.8, 2012*).

However there is an understanding on the part of the CGEN that the first of these provisions shall not apply to exotic plant species used for food or animal feed that have not acquired special characteristics *in situ* in Brazil. Thus there is agreement that registered varieties of species such as soy, corn, eucalyptus, orange and others fall outside the scope of the Provisional Act, and

specific decisions to this effect have been made in respect of sugarcane, castor bean and some other species.

Providers of genetic resources

There is as yet only interim data on quantitative aspects of some of the questions posed in the following sections on providers and users. A consultant recently carried out research on data contained in access applications to the CGEN (approved, rejected, withdrawn and pending). Data on applications to other access authorizing bodies (IBAMA, CNPq, IPHAN) have not yet been systematized.

Where are GR mostly being accessed in your country (where is the greatest demand for access to GR)? In forest areas, marine areas, other?

The 103 benefit sharing contracts approved by or lodged with the CGEN in the period 2004 to March 2013 and that have been reviewed under the consultancy show that the geographical spread is varied and covers all the biomes in Brazil (Amazonia, semi-arid, tropical savannah, Atlantic Forest, Pantanal wetlands, southern grasslands and marine), although there appears to be a predominance of forest biomes (Amazonia and Atlantic Forest). The breakdown is as follows: Amazonia 40 contracts, Atlantic Forest 38, Central Savannahs (Cerrado) 5, Semi-arid (Caatinga) 4, Marine and Coastal 2, Marine 1, Pantanal wetlands 2, Savannahs/Atlantic Forest 5, Savannahs/Semi-arid 1, Semi-arid/Atlantic Forest 1, others 4.

The geographical spread of the scientific research authorizations approved by the other bodies has not been analysed.

Do foreigners carry out bioprospection in your country or do they access genetic resources from intermediaries (e.g. ex situ collections, universities or national research institutes)? In other words are GR accessed in situ or ex situ by foreigners?

[For “bioprospection” read ”collection”, for ”access” read ”obtain”.] As previously described, foreign institutions or researchers may only participate in collecting activities in Brazil in accordance with the provisions of the Provisional Act as far as the ABS aspects are concerned and in accordance with the overall legislation on foreign participation in scientific expeditions and research in Brazil, as administered by the CNPq.

As far as the ABS aspects are concerned the foreign institution may participate in collecting and access activities in partnership with a Brazilian institution, where the Brazilian institution is the lead partner, the applicant for authorization and legally responsible. All institutions involved need to meet the institutional criteria – prior experience in biology, necessary infrastructure, facilities and skills.

Do intermediaries play an important role for ABS in your country (e.g. universities, research institutes, ex situ collections)

If what is meant in this case by intermediaries are institutions other than bodies of the executive branch (i.e. federal ministries, state or municipal secretariats), the answer is clearly yes.

The sections below give tentative data on providers and users. Providers seem in the main to be private landholders and local communities, with official bodies of the three levels of government (federal, state, municipal) figuring when collection occurs in protected areas.

Users appear to be in the majority public university and research institutions, followed by private sector applicants.

The system requires that applicants for access identify an accredited trustee institution that has agreed to receive and include in a permanent *ex situ* collection a voucher specimen of the genetic resources being accessed. Currently over 350 collections have been accredited. Their parent institutions are overwhelmingly public universities and research institutions. The trustee institutions do not play a role in the decision on authorizing access by the applicant, rather they provide a guarantee that a voucher specimen of the genetic resource in question will be permanently kept under appropriate conditions so as to permit further access and taxonomic research.

Who are the main providers of GR accessed in situ in your country: the State? Private landowners? Indigenous and local communities?

The analysis of 103 benefit sharing contracts submitted to the CGEN up to March 2013 (70 approved in the period 2004-2012 and 33 under examination) shows that in 61 cases the provider was a community association or cooperative and one was an indigenous community. A further 52 provider parties were identified, mostly private individuals or companies. (The total number of provider parties identified is greater than the number of contracts as some contracts involve more than one provider.)

Users of genetic resources

Who are the main users of genetic resources in your country? The research community, the private sector? For what purpose do they access GR, (e.g. basic research, commercialization)? Are they mostly foreigners or nationals?

The same analysis of 103 contracts shows the following breakdown of the user sectors involved: cosmetics 79; pharmaceutical research (public) 10; pharmaceuticals (private) 4; joint cosmetics and pharmaceuticals 3; others 6; unidentified 1.

The purposes of the access are: raw materials 20; research 14; final product 64; raw materials and final product 5.

As previously explained, under current legislation foreign institutions can only access Brazilian genetic resources in partnership with Brazilian institutions. There appear to be few examples of such partnerships, and some of those that exist may be partnerships between an overseas parent company and its Brazilian subsidiary.

However the number of access authorizations for scientific research involving genetic resources or traditional knowledge with no commercial intent is far greater than the number of applications considered by the CGEN. In the three year period 2010-2012 IBAMA, CNPq and IPHAN approved between them 1057 research authorizations. These do not require a benefit sharing contract and thus are not include in the above cited study.

If GR are accessed for commercial purposes, what types of sectors are interested in these GR (e.g. pharma, cosmetics, agriculture, industrial biotech)?

See above. There has been a preponderance of applications from the cosmetics and pharmaceutical sectors. There have been few applications from industrial and biotechnology sectors.

Does the national ABS system in place also address the obligation of your country as user of genetic resources accessed in foreign countries? In other words, are obligations imposed on users in your jurisdiction who have accessed GR in foreign countries to respect ABS requirements of foreign countries?

Access to genetic material obtained from international centres or third countries and that has not been collected in Brazil is exempt from the requirements of authorization.

ABS agreements

How many ABS agreements have been concluded? Is this information recorded? If not, please provide an indication.
Were these ABS agreements for non-commercial or commercial utilization of GR?

The CGEN Secretariat publishes an annual report of its activities including statistical data on access authorizations approved and rejected, benefit-sharing contracts approved, and accreditations of trustee repository institutions. Although the 2013 report is not yet publicly available, the data are as follows:

- in the period 2002-2013 1314 authorizations for access were issued by the CGEN, IBAMA, CNPq and IPHAN;
- CGEN issued 257 authorizations (for access to genetic resources with no associated traditional knowledge involved for the purposes of bioprospecting or technological development; for access to genetic resources and associated traditional knowledge for the purposes of scientific research, bioprospecting or technological development; and for access to traditional knowledge but not genetic resources for the purposes of bioprospecting or technological development);
- IBAMA issued 806 authorizations (for access to genetic resources with no associated traditional knowledge for the purposes of research);
- CNPq issued 224 authorizations (for access to genetic resources with no associated traditional knowledge for the purposes of research, bioprospecting or technological development); and
- IPHAN issued 27 authorizations (for access to traditional knowledge but not genetic resources for the purposes of research).

The 1314 authorizations can be categorized as follows:

- 40.6% - scientific research with no associated traditional knowledge
- 5.9% - scientific research involving traditional knowledge
- 0.9% - bioprospecting with no associated traditional knowledge
- 0.3% - bioprospecting involving traditional knowledge
- 2.6% - technological development with no associated traditional knowledge
- 0.1% - technological development involving traditional knowledge
- 4.2% - bioprospecting and technological development with no associated traditional knowledge
- 0.5% - bioprospecting and technological development involving traditional knowledge
- 0.1% - scientific research, bioprospecting and technological development with no associated traditional knowledge
- 0.3% - special authorizations for establishing or integrating ex-situ collections
- 40.8% - special authorizations for scientific research
- 3.8% - special authorizations for bioprospecting.

During the same period 98 CURBs were registered, of which eleven involved associated traditional knowledge. 29 CURBs were registered in the period 2004-2011, 34 in 2012 and 35 in 2013, of which two involved associated traditional knowledge. The breakdown of the 34 contracts approved in 2012 is as follows:

- 32 genetic heritage (10 technological development, 22 bioprospecting and technological development)
- 1 associated traditional knowledge (1 technological development, 2 bioprospecting and technological development)
- 1 genetic heritage and associated traditional knowledge (1 bioprospecting, 1 technological development, 4 bioprospecting and technological development).

Were any benefits derived from these agreements?

There has been no systematic survey of benefit flows and the analysis of existing contracts recently undertaken concludes that identifying the real experience of benefit sharing is hampered by a lack of data and of any existing obligation on parties to inform the CGEN of what benefits have accrued and how these have been shared.

What are the types of benefits generated from these ABS agreements? Monetary, non-monetary? How are they shared? What type of support, if any, is provided to beneficiaries receiving benefits arising from MAT and ABS agreements?

The analysis of the 103 contracts studied shows the breakdown of agreed benefits to be shared as follows: mixed monetary and non-monetary benefits 72; monetary benefits 15; potential monetary benefits 12; potential mixed monetary and non-monetary benefits 3; unspecified 1. Potential benefits are those which are agreed under the contract but where no benefit sharing has yet occurred or cannot be verified.

Sixty cases were found where monetary benefits were agreed on the basis of a percentage (varying from 0.05% to 5%) of net earnings. Of these 53 stipulated a percentage lower than that of the ITPGRFA reference value (0.77%).

Examples of implemented ABS agreements

Examples found in the analysis include:

- “Fixed value payment of [***]. The Association will enjoy exclusivity in the supply of the product. The user will fund the forest certification procedure. The community will receive payment equivalent to 0.5% of the net earnings deriving from the sale of products containing the resin.”

- “Should commercialization occur, benefit sharing is to be provided for and the rate of benefits to accrue to the Federal Government, the formula to be used in calculating the benefit, the transfer procedures and the duration are to be stipulated by means of an addendum to the contract. The benefits may include non-monetary benefits of up to 50% of receipts with the proviso that IBAMA will determine the goods and services that constitute such benefits.”

- The percentage to be applied to the net receipts from the sale of products that contain the [***] active essential oil:
    - 0.15% in the case of products containing the name of the active ingredient on the product label;
    - 0.05% in the case of products that contain the active ingredient in their composition without mentioning the name on the label.

  Part of the value generated will be allocated to the establishment of the protected area's deliberative council provided for by the reservation's management plan. The balance will be deposited in the provider's bank account. The provider is responsible for determining the projects to be supported by the monies received, but these must comply with current legislation and the principles of the CBD."

- "Setting up an *in situ* collection of regional species. Human resource training and technical assistance for the maintenance and expansion of the collection and a contribution to the upgrading of the infrastructure for drying specimens. Additionally the donation of seedlings of existing medicinal species to the current collection."

- "The provider requires that all payments under the rubric of benefit sharing be applied to projects for the conservation and sustainable use of biodiversity with the aims of (a) improving the management of areas where species *** is found, (b) supporting social organization and strengthening the supply chain, (c) valuing traditional knowledge, (d) benefitting all the localities involved, (e) carried out by participative means involving producers, representatives, users and third parties."

Have these ABS agreements contributed to conservation and sustainable use of biological diversity in your country?

Hard evidence is difficult to come by. However 34 of the 103 contracts examined provide for benefits with socio-environmental or conservation objectives; examples of which are given above.

Key lessons learned

What will you do differently in future?

The current framework was implemented as a response to a particular situation that arose in 2000 and exposed a legal vacuum that needed to be closed as a matter of urgency. The overriding purpose of the Provisional Act in force since 2001 is one of safeguarding national genetic heritage against the possibility of unregulated access and generation of benefits that are not shared with the provider country or the on-the-ground providers of the genetic resource or the holders of the associated traditional knowledge. The underlying philosophy for achieving this is a reliance on command and control procedures.

The experience of the decade between the first edition of provisional legislation in 2000 and the adoption of a binding international ABS framework in the form of the Nagoya Protocol in 2010 brought to light a number of issues:

- The confirmation that overly bureaucratic requirements are a disincentive to applied research and development for both academia and industry;
- The absence of agreed global obligations and rules of procedure on ABS encouraged many researchers and organizations to not adhere to the requirements of the Provisional Act;
- The lack of clear procedures for bringing into compliance cases of access which did not conform to the requirements of the Provisional Act or that took place before June 2000.

Much of the earlier complaints from the scientific community that the rules on access to genetic resources implemented after 2001 had a negative impact on basic research, making compliance with the procedures a cumbersome and slow process with high transaction costs, have been attenuated by the differentiated procedures subsequently introduced that distinguish between access for scientific research and access with economic intent.

Procedures have been put in place to offer institutions whose access activities do not comply with the Provisional Act, or which began before its entry into force, ways to regularize their situation.

However a number of complicated issues still need to be addressed:

- How should benefit sharing be addressed in cases where communities share a given genetic resource and/or associated traditional knowledge?
- How to determine what are fair and equitable benefit sharing models for different access situations?
- What is a fair and equitable benefit sharing model when the beneficiary is the State?
- How to deal with traditional knowledge that has already been made publicly available?
- How to achieve the right balance between command and control measures and incentive measures?
- How to treat special situations in the agriculture and health sectors?

The prospect of the entry into force of the Nagoya Protocol opens up new perspectives for countries in Brazil's situation – biologically and culturally megadiverse and with genetic resources forming a key element of its national science, technology and innovation policy. It offers:

- The prospect of a legally-binding global regime on ABS;
- A clear definition of the scope of the ABS regime (beyond genes and including traditional knowledge)
- Defined relationships with other treaties;
- An ABS clearing-house mechanism;
- International Certificates
- A possible global fund (multilateral mechanism)
- The commitment of users countries
- The prospect of legal certainty

The current phase of ABS policy development in Brazil includes seeking ratification of the Nagoya Protocol by Congress and its incorporation into national law and the preparation by the federal government of a draft new ABS law for submission to Congress.

Prior to the adoption of the Protocol in 2008 the federal government put out a draft of a new ABS law for public consultation. Substantial comments were received and the main stakeholder sectors continue to be actively involved in the current drafting process – organizations representing the scientific community, indigenous and traditional communities, industrial user groups and the agricultural sector.

Inter-ministerial discussions on a new draft for submission to Congress are at an advanced stage and changes to existing procedures are currently expected to include:

- The distinction currently made between access for research, for bioprospecting or for technological development will no longer apply;
- Research and technological development involving genetic resources will be subject to electronic registration procedures;
- Research on associated traditional knowledge will be subject to registration; proof of registration will be required for publication;
- Proof of prior consent will be required only in cases of access to associated traditional knowledge;
- The CURB will become the ARB (*Acordo de Repartição de Benefícios* - Benefit Sharing Agreement), which will be required prior to the marketing of any product deriving from the access;
- The CGEN will issue a certificate of authorized access when an ARB is registered; this certificate will be required for registering products and for patent applications;
- Overseas shipment of genetic resources will require registration; domestic shipments will be exempt;
- Overseas institutions will be able to apply directly for access authorization without the need for association with a Brazilian partner institution;
- Benefits arising from the use of diffuse associated traditional knowledge will be paid into a benefit sharing fund;

- Calculation of benefits to be shared will be based on a fixed percentage to be shared with the Union and paid into a benefit sharing fund; the owner of the area where collection occurred will cease to be a beneficiary;
- The benefit sharing fund will support projects; a National Benefit Sharing Programme will be established; local communities will be represented on the fund management body and in CGEN working groups;
- Tax incentives will be introduced to promote investment in science and technology;
- In the case of plant genetic resources for food and agriculture benefit-sharing will apply to the sale of reproductive material in accordance with the provisions of the ITPGRFA;
- Farmers' rights and traditional knowledge of local varieties and landraces will be recognized;
- The provisions of the Provisional Act on non-compliance (Article 26) will be withdrawn; non-compliance will be addressed on a case-by-case basis when a complaint is lodged within a pre-determined timeframe.

It should be stressed however that, although the inter-ministerial negotiations are well-advanced, they have not yet concluded. Were the government to reach consensus and submit the bill to Congress in the near future, the fact that 2014 is a general election year makes it optimistic to assume that Congress would be able to conclude the legislative process during 2014.

Pending the conclusion of the drafting process of a new ABS law and the process of ratification of the Nagoya Protocol, a number of steps are being taken to improve the operations of the current legislation and procedures:

- Further adjustments to the procedures under the Provisional Act aiming at less bureaucracy, clearer procedures and clearer guidelines;
- Capacity building and awareness raising;
- Reviews of best practices on ABS governance structure and procedures;
- Dialogue with the EU (Commission and selected member states), India and South Africa on national ABS frameworks and ratification of the Nagoya Protocol;
- Examination of ways to create stronger incentives for R&D based on genetic resources and traditional knowledge.

Annex 1

Institutional actors

1: Genetic Heritage Management Council (*Conselho de Gestão do Patrimônio Genético – CGEN*)

Members:

- Ministry of the Environment (*Ministério do Meio Ambiente – MMA*)
- Ministry of Agriculture, Livestock and Supply (*Ministério da Agricultura, Pecuária e Abastecimento – MAPA*)
- Ministry of Science, Technology and Innovation (*Ministério da Ciência, Tecnologia e Inovação – MCTI*)
- Ministry of Culture (*Ministério da Cultura – MinC*)
- Ministry of Defence (*Ministério da Defesa – MD*)
- Ministry of Justice (*Ministério da Justiça – MJ*)
- Ministry of Health (*Ministério da Saúde – MS*)
- Ministry of External Relations (*Ministério das Relações Exteriores – MRE*)
- Ministry of Development, Industry and Foreign Trade (*Ministério do Desenvolvimento, Indústria e Comércio Exterior – MDIC*)
- National Council for Scientific and Technological Development (*Conselho Nacional de Desenvolvimento Científico e Tecnológico – CNPq*)[2]
- Brazilian Agricultural Research Corporation (*Empresa Brasileira de Pesquisa Agropecuária – EMBRAPA*)
- Palmares Cultural Foundation (*Fundação Cultural Palmares – FCP*)[3]
- National Indian Foundation (*Fundação Nacional do Índio – FUNAI*)[4]
- Oswaldo Cruz Foundation (*Fundação Oswaldo Cruz – FIOCRUZ*)[5]
- Brazilian Institute for the Environment and Renewable Natural Resources (*Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis – IBAMA*)[6]
- Rio de Janeiro Botanical Garden Research Institute (*Instituto de Pesquisas Jardim Botânico do Rio de Janeiro – JBRJ)*
- Evandro Chagas Institute (*Instituto Evandro Chagas – IEC*)[7]
- National Institute for Research on the Amazon (*Instituto Nacional de Pesquisas da Amazônia – INPA*)

[2] Attached to the Ministry of Science, Technology and Innovation
[3] Federal agency responsible for the promotion and preservation of Afro-Brazilian art and culture, attached to the Ministry of Culture
[4] Federal agency responsible for the implementation of policies for indigenous peoples, attached to the Ministry of Justice
[5] Federal health research and development institution attached to the Ministry of Health
[6] Federal environmental protection agency attached to the Ministry of the Environment
[7] Biomedical research and public health institute attached to the Ministry of Health

- National Institute for Industrial Property (*Instituto Nacional de Propriedade Industrial – INPI*)

Permanent observers

- Business Movement for the Conservation and Sustainable Use of Biodiversity (*Movimento Empresarial pela Conservação e Uso Sustentável da Biodiversidade – MEEB*)
- Brazilian Association of State Environment Bodies (*Associação Brasileira de Entidades Estaduais de Meio Ambiente – ABEMA*)
- Brazilian Business Council for Sustainable Development (*Conselho Empresarial Brasileiro para o Desenvolvimento Sustentável – CEBDS*)
- National Council of Agro-extractive Communities (*Conselho Nacional das Populações Extrativistas – CNS*)
- Coordinating Body of Indigenous Organizations of the Brazilian Amazon (*Coordenação das Organizações Indígenas da Amazônia Brasileira – COIAB*)
- National Coordinating Body of the Network of Rural Black Maroon Communities (*Coordenação Nacional de Articulação das Comunidades Negras Rurais Quilombolas – CONAQ*)
- Brazilian Pharmeceutical Industry Federation (*Federação Brasileira da Indústria Farmacêutica – FEBRAFARMA*)
- Federal Prosecutor-General's Office (*Ministério Público Federal*)
- Brazilian Society for the Advancement of Science (*Sociedade Brasileira para o Progresso da Ciência – SBPC*)
- Brazilian Forum of NGOs and Social Movements for the Environment and Sustainable Development (*Fórum Brasileiro de ONGs e Movimentos Sociais para o Meio Ambiente e Desenvolvimento Sustentável – FBOMS*)

2: Accredited bodies for the issue of access authorizations

- CGEN (Genetic Heritage Management Council)
- IBAMA (Brazilian Institute for the Environment and Renewable Natural Resources)
- CNPq (National Council for Scientific and Technological Development)
- IPHAN (Institute for National Historical and Artistic Heritage)

3: Other bodies that need to approve in-situ collection under specific circumstances

- ICMBio (Chico Mendes Institute for Biodiversity Conservation)
- FUNAI (National Indian Foundation)
- JBRJ (Rio de Janeiro Botanical Garden Research Institute)
- Marinha do Brasil (Brazilian Navy)
- Conselho de Defesa Nacional (National Defence Council)

3: Trustee institutions (*Fiéis depositários*)

- 192 institutions holding 358 ex-situ collections

Annex 2

Applying for access authorization

1: prior agreement with provider

a: access to be carried out on resources to be collected in-situ

Place of collection	*Access and benefit sharing agreement with*
Conservation area (federal, state, municipal)	Management authority*
Indigenous area	Community and FUNAI
Private land	Landowner*
National security area	National Defence Council
Marine area, continental shelf, EEZ	Navy

* Depending on its land tenure situation, collecting on lands belonging to a traditional community may occur in a conservation area or on private land.

b: access to be carried on resources held in an ex-situ collection

Genetic resource deposited in collection	*Provider known?*	*Access and benefit sharing agreement with*
Prior to Provisional Act (2001)	yes	Original provider*
	no	Ex-situ collection
After entry into force of Provisional Act	yes	Original provider*
	no	To be decided by CGEN

* If originally collected in a conservation area, indigenous land, marine area, continental shelf or EEZ, CGEN to decide

c: nature of species involved

Is species involved	*If yes*	*Authorization from*
Endemic, threatened or CITES-listed?	fauna	IBAMA
	flora	JBRJ

2: in-situ collection for scientific research with no access involved (i.e. involving no activity that seeks to isolate, identify or use information of genetic origin or molecules and substances deriving from the metabolism of living beings and of extracts obtained from these organisms)

Collecting to occur in:	*Authorization*
Federal conservation areas or subterranean caverns	Through the SISBio system
Other areas	Landowner, community or management authority

3: application for authorization for access

Resources involved	*Purpose of access*	*Application to:*
Genetic resources with no associated traditional knowledge	research	IBAMA or CNPq
	bioprospecting	CGEN or CNPq
	technological development	CGEN or CNPq
Genetic resources and associated traditional knowledge	research	CGEN
	bioprospecting	CGEN
	technological development	CGEN
Associated traditional knowledge but no genetic resources	research	IPHAN
	bioprospecting	CGEN
	technological development	CGEN

Annex 3

Glossary

CGEN	Genetic Heritage Management Council (*Conselho de Gestão do Patrimônio Genético*)
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CNPq	National Council for Scientific and Technological Development (*Conselho Nacional de Desenvolvimento Científico e Tecnológico*)
CURB	Utilization of Genetic Heritage and Benefit Sharing Contract (*Contrato de Utilização do Patrimônio Genético e de Repartição de Benefícios*)
EEZ	Exclusive Economic Zone
FUNAI	National Indian Foundation (*Fundação Nacional do Índio*)
IBAMA	Brazilian Institute for the Environment and Renewable Natural Resources (*Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis*)
ICMBio	Chico Mendes Institute for Biodiversity Conservation (*Instituto Chico Mendes de Conservação da Biodiversidade*)
ILO	International Labour Organization
INPI	National Institute for Industrial Property (*Instituto Nacional de Propriedade Industrial*)
IPHAN	Institute for National Historical and Artistic Heritage (*Instituto de Patrimônio Histórico e Artístico Nacional*)
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
JBRJ	Rio de Janeiro Botanical Garden Research Institute (*Instituto de Pesquisas Jardim Botânico do Rio de Janeiro*)
MAT	Mutually-agreed terms
MP	Provisional Act (*Medida Provisória*)
NP	Nagoya Protocol
PIC	Prior informed consent
SISBio	Biodiversity Authorization and Information System (*Sistema de Autorização e Informação em Biodiversidade*)
TK	Traditional knowledge