IMPLEMENTATION OF THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING

Dialogue between Brazil and the European Union

SECTOR DIALOGUES
EUROPEAN UNION
BRAZIL

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Context

How can countries ensure that they benefit from the use of their genetic resources by others? No benefits from use can arise if no use is made, but history tends to show that benefits do not necessarily flow from users to providers without prompts, incentives, checks and penalties.

Brazil and European countries have exchanged genetic resources for centuries. There is strong mutual recognition of the potential benefits that can be created and shared through greater academic and commercial exchange.

The Nagoya Protocol provides a new framework for these relationships, adding clarity and force to the original access and benefit-sharing (ABS) provisions of the Convention on Biological Diversity. Countries that have exercised their sovereign right to decide how others may access their genetic resources must set out clear measures; countries where genetic resources are utilised must ensure that users are complying with those providers' measures. To support compliance, the Nagoya Protocol establishes the structures for an international system to monitor the utilisation of genetic resources.

The EU and many European countries have ratified the Protocol and Brazil is expected to ratify in due course. Brazil and the European Union have developed new legal measures in response to the Protocol. Exactly how these measures will function together between countries and across sectors is not yet known. A first step is for all actors to understand what these regulations require, and how the requirements can be handled in practice. Sectors differ in their use and management of genetic resources, and sectoral measures such as contractual agreements and best practices can supplement and support these legal measures, so understanding how the measures will work can only be achieved through input from a wide range of users.

Tracking and tracing methods are essential for monitoring utilisation under the new legal frameworks, so that Brazilian resources remain linked to their source information as they travel, users in the EU can determine the history and legal background of the resources they wish to use, and benefits that arise can be shared with Brazil. Sectoral tracking practices and capacities need to be considered so that global and national monitoring systems are efficient and cost-effective for providers and users.

Although explicitly framed as a Brazil-EU dialogue, the issues addressed here are generic and could be considered as applicable to all Parties to the Protocol.

The Project

The Brazil-EU project 'Implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing – Fourth Phase,' conducted April-July 2016, continued the dialogue between Brazilian and European governments and sectoral experts. This fourth phase specifically aimed to strengthen the regulatory capacities of Brazil and the EU by promoting the traceability of genetic resource samples through the research and product development chain.

To achieve this overarching objective, the project focussed on how information about the origin and conditions of access to genetic resources is made available along the supply and value chain, and how information on utilisation and benefit generation are made available to Brazil (tracking, tracing and monitoring). While the Nagoya Protocol provides generic solutions, the detail is found in national or regional regulations and laws, and in stakeholder activities. It is in comparison of these that mismatches of expectation and requirements can be found and addressed, to the benefit of all. The project therefore sought to (i) characterise the main features and properties of tracking and monitoring systems for the providers and users of genetic resources (ii) identify the necessary workflows to manage

such a system, and (iii) discuss and characterise their main features to ensure practical implementation, including through interoperability with other systems, such as the ABS Clearing House of the Convention on Biological Diversity. It also considered robust and simplified mechanisms and tools to comply with the Nagoya Protocol, with the expectation that such tools would (i) provide legal certainty and consequently (ii) increase the interest and investment in knowledge and bioprospecting of Brazilian biological diversity, stimulating scientific and technological exchanges between Brazil and the EU, while (iii) protecting the interests of all stakeholders. This in turn would contribute to conservation and sustainable use of Brazil's outstanding biodiversity.

The project examined the new monitoring systems established by: the Nagoya Protocol; Brazilian Law 13.123/2015, which sets out a new access regime based on a registration process; and European Union Regulation (EU) 511/2014, which sets out a compliance system for users in EU Member States based on due diligence measures. The Law and the Regulation are both now in force, although comprehensive systems for implementation between different Brazilian agencies and in some EU Member States are not yet finalised. Brazilian Decree 8.772/2016, setting out implementation measures for Brazilian Law 13.123, was promulgated during the early stages of the project.

The dialogues focused on how these legislative measures for monitoring genetic resource utilisation will function together, rather than in isolation, and what level and kind of tracking and/or tracing are necessary to comply with them and achieve the Protocol's benefit-sharing objective.

The project activities comprised:

- A background paper on the legal frameworks for monitoring and sectoral tracking/tracing practices, to support workshop discussions[1];
- A Brasília workshop, with wide cross-departmental and cross-sectoral participation, including EU and SCBD representatives[2];
- A London workshop, with cross-sectoral EU participation and Brazilian representatives, in which three carefully-designed hypothetical case studies were used to explore how legislation and sectoral systems would apply[3];
- A meeting in the EU Commission in Brussels to present and

1. https://www.embrapa.br/recursos-geneticos-ebiotecnologia/dialogo-protocolo-de-nagoya
2. https://www.embrapa.br/recursos-geneticos-ebiotecnologia/dialogo-protocolo-de-nagoya
3. http://nagoyaprotocol.myspecies.info/node/23

discuss with EU Member State representatives the Brazilian law and EU Member States' ABS measures.

Brasília workshop

The Brasília workshop, conducted at Embrapa Genetic Resources and Biotechnology, began with formal presentations from Brazilian government and invited EU government, CBD Secretariat and sectoral representatives. Two days of working group discussions followed, in plenary with Portuguese-English translation. The workshop concluded with a final day featuring the transmission of the results of the working group in a public communication seminar. Due to the very recent release of the Decree, the working group was provided with the opportunity to query representatives of the Ministry of the Environment as to how the new Brazilian access system is envisioned to function, to provide firmer ground for subsequent discussion of other questions.

The principal questions addressed by the working group were: (1) What is the purpose of monitoring and tracking genetic resources, from the Brazilian perspective? (2) What are the characteristics of a workable tracking/traceability system – and what level and kind of tracking/tracing is needed for compliance with Brazilian and EU monitoring requirements? (3) What could the simplest system that would meet Nagoya Protocol/EU/Brazil requirements look like? (4) What identifiers are needed for the ABS system to work – to what should they be applied and do they need to be globally unique? (5) What is the role of best practices in the tracking/monitoring context?

The working group's results included clarifications regarding the Brazilian law and a set of recommendations for further action, including the establishment of an inter-agency, cross-sectoral Task Force to find ways to share, simplify and coordinate access-related processes in Brazil, such as collection, transfer and export.

London workshop

The London workshop, conducted at the Natural History Museum, involved Brazilian Government representatives and EU sectoral representatives, several of whom had also participated in the Brasília workshop. The London workshop aimed to: (1) inform EU representatives of new legislation in Brazil; (2) inform Brazilian representatives of EU legislation and its implications for ABS compliance in R&D in the EU; (3) identify issues of tracking and tracing GR and ATK originating in Brazil and being used in the EU; (4) explore expectations and understanding associated with legal and contractual obligations, noting any differences in expectations

between different stakeholder groups; and (5) identify areas of concern for further action, proposing solutions where possible.

After formal presentations from Brazilian and EU representatives on the Brazilian and EU legislation and short presentations on sectoral tracking and tracing systems, participants discussed the requirements and systems from provider country and user perspectives. On the second day, three working groups discussed hypothetical case studies involving the acquisition and use of genetic resources (Box 1).

Brussels Meeting

The Brussels meeting enabled Brazilian and EU representatives from the European Commission and Member State checkpoints to exchange information about their respective measures, including how the EU compliance measures are being implemented in each country.

Box 1: Case studies explored in the project

The London workshop presented three case studies, all hypothetical but containing likely real-world scenarios. For each, participants were asked to consider the supply and value chain activities from access to the end of utilisation and commercialisation, if it occurs, and questions were posed regarding the responsibilities and expectations of each of the stakeholders - Providers, Regulators, and Users.

Participants were encouraged to consider the perspectives of the stakeholders (how significant the situation is for each actor, how they will know what to do in their workflow); whether there are soft solutions that need to be embedded in organisational policies or sectoral best practice; how tracking/tracing/monitoring systems, if they are in place, should operate between different actors, or if there are reasons (e.g. confidentiality) that might militate against their use.

Case study 1: Academic study and potential commercialisation

A researcher is studying venom in the UK, particularly its biochemical properties, to inform his grant-funded taxonomic research. He accesses Brazilian snakes in situ and from a British pet shop for non-commercial research; the snakes from the pet shop include both wild-caught specimens and their progeny. He partners with other research organisations (one in Germany, one in Australia) to obtain access to their analytical facilities, since he is unable to analyse the chemical constitution of the venom. All his results are published, including the chemical composition of the venoms (on the publicly-available European Molecular Biology Laboratory site, EMBL). Both German and Australian organisations may have non-commercial and commercial interests, and pursue commercial lines of research with the analytical outputs. A third commercial company in the UK downloads the chemical composition data from the EMBL site, and develops a product for market.

Case study 2: Supply chain and value chain

Plant samples are collected in several countries including Brazil by a number of collectors working for an SME. These plants are sold on through an intermediary to a product development company for scientific research of potential aromatics. After analysis and screening, a set of chemicals is taken forward from these plants for modelling and synthesis. Following final selection the chemical formulae and a synthesis system are sold to a cosmetics firm for further work and eventual marketing as part of a range of beauty products. In a separate transaction, a Brazilian company extracts the sap of the plants and exports it to the EU as a health drink. An EU company purchases the drink and extracts chemicals as described above, selling the formulae on to a cosmetics company.

Case study 3: Cross-over from non-commercial to commercial

An EU researcher collects fungi in Brazil as a part of his research into factors affecting plant growth. He selected the fungi with advice from an indigenous culture (who live in Brazil and also Peru and Colombia). In the EU he extracts the active chemicals in grant-funded work. He publishes the results of his research, including the chemical composition, on a public database. Fungal cultures are transferred to a culture collection, the researcher having no further interest in them. A pharmaceutical company recognises the potential value of one of the chemicals, and is aware from published studies elsewhere that the fungus concerned is known to have traditional medical properties developed by the indigenous culture, at least in Peru. The pharmaceutical company acquires some of the strain from the culture collection, synthesises the chemical, and eventually it appears as a part of a product.

The London workshop was able to explore further the bridges and gaps between the legislative measures, and to identify key elements that have the potential to cause confusion or concern. The group also considered tracking/tracing practices in greater detail. Discussions centred on terminology, applicability of the legislation (especially regarding access to and tracking/tracing information in the public domain), how mutually agreed terms and benefit-sharing are addressed, and the use of unique identifiers. The group produced recommendations, including specific questions for Brazilian and EU authorities.

Outcomes

The project activities together progressively highlighted the regulatory bridges between Brazil and the EU, and also the potential gaps that need to be addressed for the systems to function together in practice, whether through clarification, capacity building, or even potential revision of the legal framework as more experience is gained. Although the focus was on movement of Brazilian resources from Brazil to the EU in the ABS context, the project also considered the many non-ABS actors and processes involved in the collection, transfer and export of Brazilian genetic resources.

This booklet shares information on the legal frameworks and sectoral practices, highlights insights gained and lessons learned, and sets out some of the recommendations that emerged through the process. Although this project specifically concerns Brazil and the EU, this methodology for cross-sectoral dialogue could be applied constructively between other regions.

Legal framework

The Nagoya Protocol

The Nagoya Protocol (NP)[4] sets out elements for monitoring the utilisation of GR and associated traditional knowledge (ATK) for implementation by national and regional governments.

The NP establishes the **Access and Benefit-Sharing Clearing House (ABS-CH)**[5], an information-sharing mechanism that plays a central role in the global monitoring of ABS actions.

NP Parties that regulate access are able to publish their national access permits, or equivalents, on the ABS-CH. This action generates **Internationally Recognised Certificates of Compliance (IRCCs)**. IRCCs are trackable permits with unique identifiers that link to ABS-relevant information, including the source, the provider of prior informed consent (PIC) and initial user, and details of mutually

4. https://www.cbd.int/abs/text/default.shtml
5. https://absch.cbd.int/

agreed terms (MAT), although these data may not be made available on the ABS-CH if they are confidential.

The NP requires all Parties to set up at least one **checkpoint**, to collect or receive information from users relevant to Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), source and/or utilisation of GR and to pass it to the ABS-CH, if the information is not confidential, as well as to the provider of PIC and the person to whom PIC was granted, as appropriate. IRCCs provide a vehicle for much of that information.

The descriptions below of the EU Regulation on Access and Benefit-Sharing and the Brazilian ABS law and decree are not exhaustive, but highlight the areas where they intersect, and where they establish relevant requirements and expectations.

The EU Regulation

EU Regulation 511/2014[6] establishes rules to govern compliance with ABS by users in European Union Member States, and a mechanism for monitoring utilisation. Further detail is set out in Commission Implementing Regulation (EU) 2015/1866[7]. The EU Regulation does not establish access measures; Member States may choose to regulate access to their own GR/ATK or to grant free access.

The Regulation's scope is clearly defined: it covers genetic resources and/or traditional knowledge associated with genetic resources (GR/ATK) that are accessed in areas within a country's national jurisdiction, from a country that was at the time a Party to the Nagoya Protocol, with applicable access legislation, where the GR/ATK were accessed on or after 12 October 2014, are not covered by a specialised international ABS instrument, and are non-human. It is applicable to utilisation within the EU.

The Regulation defines 'access' as acquisition of GR/ATK in a Party to NP, and 'user' as a natural or legal person that utilises GR/ATK. A person who only transfers material (an intermediary) is not a user under the Regulation, and nor is a person who only commercialises products based on utilisation, although both may have contractual obligations entered into when the GR was accessed or at change of intent. The Regulation

6. Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32014R0511

7. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EUL) No 511/2014 of the European Parliament and the Council as regards the register of collections, monitoring user compliance and best practices. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

uses the NP definition of utilisation of GR and CBD definitions of GR and genetic material.

Guidance[8] on the scope of the Regulation provides examples of activities that fall, and do not fall, under the Regulation's definition of utilisation. Examples of utilisation include research on a genetic resource leading to the isolation of a biochemical compound used as a new ingredient (active or not) incorporated into a cosmetic product; a breeding programme to create a new plant variety based on landraces or naturally occurring plants; genetic modification – creation of a genetically modified animal, plant, or microorganism containing a gene from another species; and creation or improvement of yeasts, resulting from human action through a research and development process, to be used in manufacturing processes (but not including the use of yeasts 'as is' in brewing, where no research and development is carried out on the yeast). Examples of activities that are not utilisation include: supply and processing of relevant raw materials for subsequent incorporation in a product where properties of the biochemical compound contained in the GR are already known; GR as testing/reference tools; handling and storing of biological material and describing its phenotype; the application of biotechnology in a way which does not make the GR the object of research and development. The Regulation's definition of utilisation also does not cover material such as synthetic gene segments (as they are not naturally occurring). Research and development on derivatives is within scope where they are derived from genetic resources accessed under the Protocol, covered by the required prior informed consent related to genetic resources from which they were derived, and addressed in mutually agreed terms. The guidance document suggests that, without prejudice to the outcome of ongoing discussions by Parties to the Protocol, the use of digital data obtained from gene sequencing could be considered to be out of scope of the Regulation.

Users are obliged to exercise due diligence to ascertain that GR/ATK which they utilise have been accessed in accordance with applicable ABS legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements. They must seek, keep and transfer the

8. Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2016/C 313/01), available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2016:313:TOC.

IRCC and information on the content of MAT relevant for subsequent users or, if no IRCC is available, other information and relevant documents (on date and place of access, the GR/ATK utilised, source, access permits, presence or absence of ABS rights and obligations, MAT). If they have insufficient information or uncertainties about the legality of access and utilisation, they must obtain an access permit or its equivalent and establish MAT, or discontinue utilisation. This is a principal obligation of the Regulation that helps to ensure that the necessary information travels throughout sometimes very complex value chains.

Compliance is monitored at two key stages at which users must provide 'due diligence declarations' (DDDs) to the competent authority in a Member State[9]: (1) the stage of research funding and (2) the stage of final development of a product (Fig. 1). Due diligence declarations include information on IRCCs or equivalent information if an IRCC is not available. The competent authorities will report information from DDDs to the ABS-CH, where they will be turned into checkpoint communiqués; when the principal information is confidential (example.g. the place of access), it will be transmitted directly to the competent national authority of the provider country and not published on the ABS-CH. The DDDs also include information that is relevant to EU authorities but is not transmitted to the ABS-CH.

The Regulation does not require the reporting of transfers of GR/ATK along a chain (or network) of custody. The guidance document clarifies that transfers of the results or outcomes of utilisation between entities of the same company do not require the filing of a DDD (such transfers are not considered as transfer in the meaning of the Implementing Regulation (Art. 6(2)(d) and Art. 6(2)(e)). Neither does the publication of scientific papers require a DDD, as it is not considered as fulfilling the criteria of being sold or transferred in the meaning of the Implementing Regulation (though the general due diligence obligation may still apply).

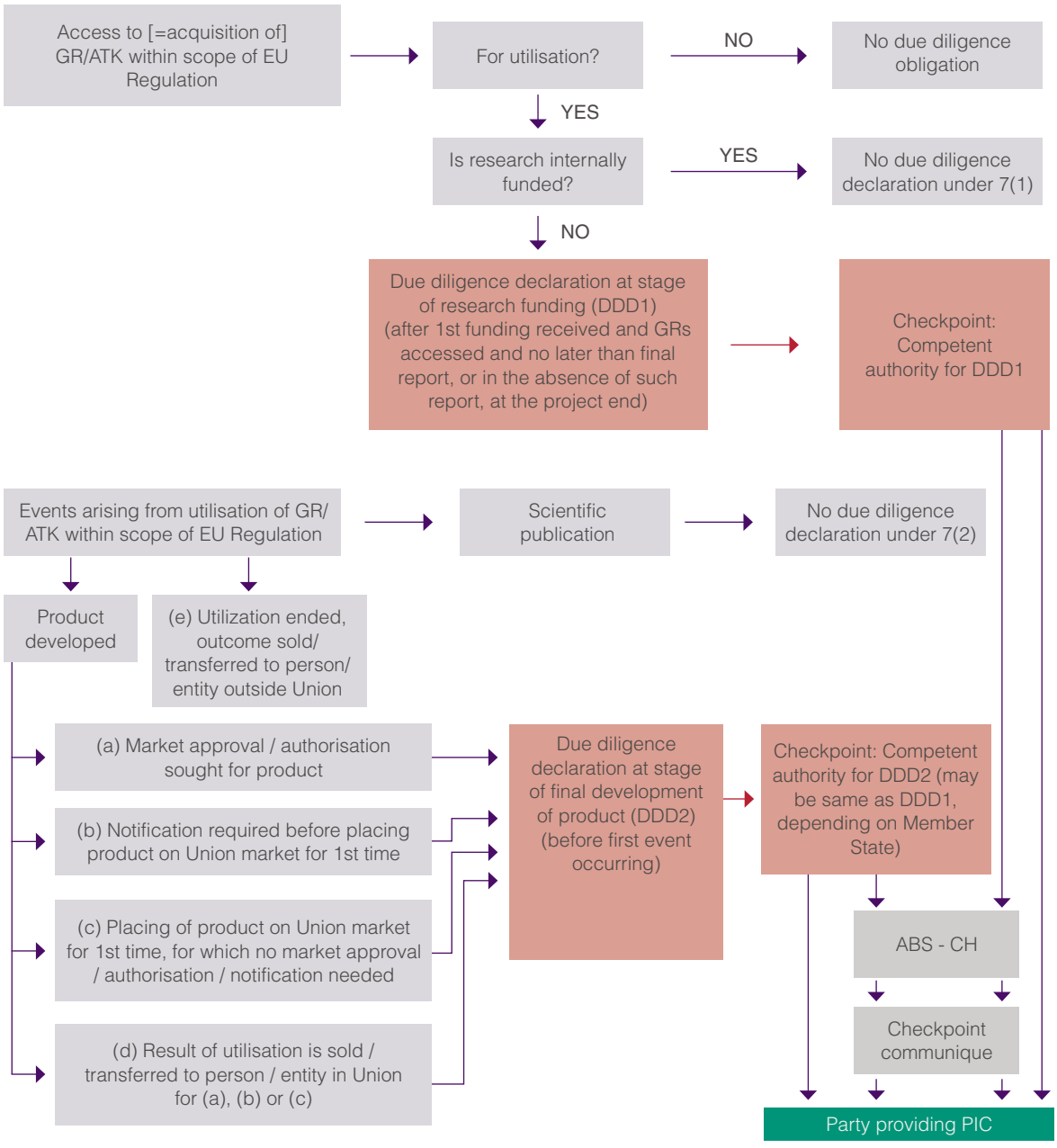
An online system 'DECLARE' is being developed as the means to submit the DDDs. The system uses the EU Commission's Environment Data Submission Portal, which covers the Nagoya Protocol as well as other policy domains. DECLARE will streamline the collection, validation, analysis and dissemination of (among other information) due diligence declarations and information on the submitting organisations. It will assist the EU

9. The authorities to whom the DDD are to be submitted are defined in the Implementing Regulation.

Member States' competent authorities in feeding the appropriate information into the ABS Clearing-House, where it will published as Checkpoint Communiqués.

In addition, the competent authorities of the EU Member States are under duty to carry out checks to verify compliance, i.e. whether users comply with their obligation to exercise due diligence and to file due diligence declarations. Those checks need to be effective, proportionate, dissuasive, and detect cases of user non-compliance with the Regulation. Furthermore, penalties for non-compliance with the EU ABS Regulation have been set up in many Member States (and are being set up in others).

Figure 1: Stages at which the EU Regulation monitors compliance via due diligence declarations.



*When information would not be published on theABS-CH due to confidentiality reasons

Under the EU Regulation the European Commission establishes a **register of collections**, to which collections, upon their holder´s request, are added if they meet certain requirements, including the capacity to apply standardised procedures for exchanging and supplying samples of GR and related information in line with the CBD and the NP, to use unique identifiers (where possible) for samples supplied, and to use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections. Their ability to do so will be checked regularly by the competent authorities of the Member States, using a risk-based approach.

The Regulation also encourages associations of users to apply for **recognition of best practices**, developed at a sectoral level to help users meet the obligations for due diligence. Applications are submitted to the EU Commission, and the competent authorities of all Member States may comment on them before a decision to grant recognition is made.

About half of EU Member States have established the national laws and structures necessary for implementation. Others are still in the process of doing so.

Brazilian Legislation

The Brazilian ABS legislation is underpinned by Law 13.123[10] of May 20th 2015, which came into force on November 17th 2015. It repeals the former Brazilian Biodiversity Law (Provisional Measure 2.186, 2001) and its implementation is regulated by Decree 8.772[11] of 11 May 2016. The legislation addresses access, not compliance with access provisions in other countries, and its definition of access refers to research and technological development, not acquisition.

The new legislation is based on a registration and notification system. The Genetic Heritage Management Council (CGen) of the Ministry of Environment has an important role managing ABS information that is the core of the ABS compliance. CGen will maintain the National System for Genetic Heritage and Associated Traditional Knowledge Management – SisGen, an online system. Users will register using SisGen while accessing or shipping Brazilian Genetic Heritage (GH) or traditional knowledge associated with the GH (ATK). SisGen will also be used for notification of finished products/ reproductive materials. SisGen will issue a receipt after registration or notification.

10. http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm

11. http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2016/Decreto/D8772.htm

CGen can issue, upon request by the user, a Certificate of Access Regularity for each of these events. The registration and notification mechanisms serve to monitor the utilisation of Brazilian GH and ATK but, like the EU measures, they do not constitute a detailed tracking system. Only Brazilian natural and legal persons can use SisGen.

A number of other agencies and processes are involved in the acquisition and transfer of GH/ATK within Brazil and abroad, regarding research, collection, transport, biosurveillance for health and agriculture, CITES, border crossings and postal systems.

Collecting and sampling biological resources for scientific or teaching purposes, whether or not access (research and development) is involved, may be subject to authorisation by the Chico Mendes Institute for Biodiversity Conservation (ICMBIO; see IN 03[12] for further information).

Brazilian biodiversity can only be acquired or accessed by foreign institutions (legal persons) in partnership with a Brazilian institution (public or private). Research and the collecting of GH samples in Brazil by foreigners require an Authorisation for Scientific Expeditions granted by National Council for Scientific and Technological Development (CNPq). To obtain this authorisation, the Brazilian partner institution (and responsible body for the project in Brazil) must present the application to CNPq.[13]

In certain situations, when foreign institutions/organisations are involved in access activities carried out by Brazilian natural or legal persons, access registration requires prior authorisation from the National Defence Council (for accessing GH/ATK from areas indispensable to national security) or the Maritime Authority (for accessing GH/ATK from Brazilian marine areas). This authorisation is also obtained through SisGen.

12. IN 03: Normative Instruction No. 03 of September 1st, 2014. ICMBio. Available at http://www.icmbio.gov.br/sisbio/images/stories/instrucoes_normativas/INSTRUÇÃO_NORMATIVA_ICMBio_Nº_3_DE_2014__com_retificação_do_DOU18062015.pdf

13. The procedure for requesting authorisation is available at http://cnpq.br/como-solicitar/

Definitions and Scope

Genetic Heritage: genetic information of plant, animal and microbial species or otherwise, including substances derived from the metabolism of these living beings.

Access: research or technological development carried out on a genetic heritage sample.

The temporal scope of the Brazilian Law 13.123 concerns the time of access, not the time of acquisition. Access and economic exploitation realised after 30 June 2000 and before 17 November 2015 (the period of time over which Provisional Measure 2.186-16 was applicable) must be regularised within one year after the date upon which SiSGen becomes functional[14].

The law covers the goods, rights and obligations related to:

- access to Brazilian GH obtained from in situ, ex situ and in silico conditions;
- traditional knowledge associated with GH;
- technology access and technology transfer for biodiversity conservation and utilisation;
- economic exploitation of finished products or reproductive material originating from GH or ATK access;
- the fair and equitable sharing of benefits arising from economic exploitation;
- shipment[15] abroad of samples with the intent of accessing GH;
- the implementation of international treaties on GH/ATK approved and promulgated by the National Congress.

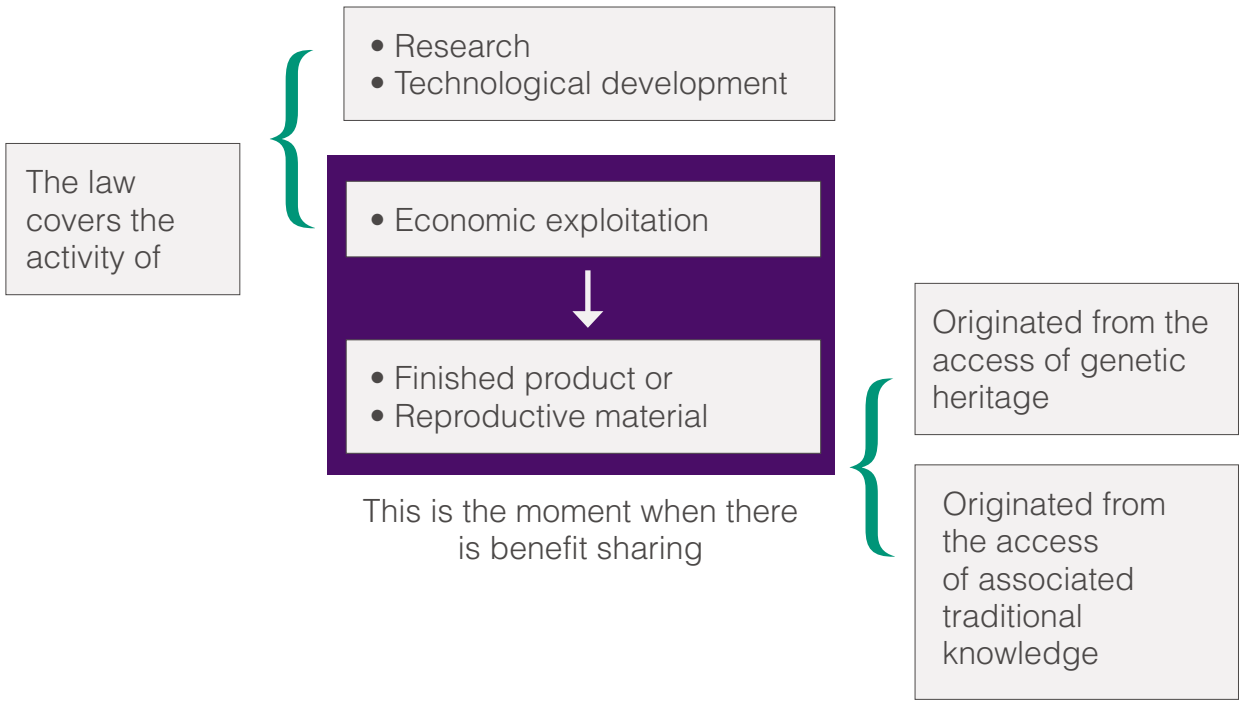
A finished product is defined as a product originating from GH/ATK access that does not require any additional production process, in which the GH or ATK component is a key element of value adding to the product, and ready for use by the final consumer, whether a natural or legal person.

An intermediate product is defined as a product used in the production chain as an input, excipient or raw material, for the development of another intermediate product or finished product.

14. For further information see Law 13.123/2015 (Arts. 35-45) and Decree 8.772/2016 (Arts. 103-104)

15. involving a change in responsibility for the sample; see section on 'Sending and Shipping'

Figure 2: Scope of the Brazilian Law.



Competent Authority

The Genetic Heritage Management Council (CGen) manages, controls and supervises activities related to GH/ATK access. CGen is a collegiate body of deliberative, normative, advisory and appellative character, responsible for coordinating the development and implementation of policies for the management of GH/ATK access and benefit sharing. CGen comprises representatives from bodies and entities of the federal public administration (55%) and civil society (45%), including ministries, business sector, academia, indigenous peoples, traditional communities and traditional farmers. CGen competences include monitoring activities such as access and shipment, registering notifications, recognising national ex situ collections, and setting technical standards for Benefit Sharing Agreements. CGen will also operate and maintain the SisGen online system.

SisGen will be used to manage:

- registration of access to GH or ATK;
- prior authorisations for access, where applicable;

- registration of international GH sample shipment for the purpose of access;
- registration of international GH sample sending by a Brazilian legal person for services provided abroad as part of research or technological development;
- notifications of finished products and reproductive material, for economic exploitation;
- Benefit Sharing Agreements;
- Certificates of Access Regularity;
- accreditation of ex situ collections institutions that maintain samples of GH.

SisGen registrations and notifications can only be made by a Brazilian natural or legal person, who may be a Brazilian user or a Brazilian acting in collaboration with an overseas user.

Access

Registration is required for access to GH or ATK

- inside the country by a Brazilian natural or legal person (public or private);
- by a legal person headquartered abroad associated with a Brazilian institution of scientific and technological research (public or private);
- conducted abroad by a Brazilian natural or legal person (public or private).

If access occurs in Brazil and involves a foreign researcher, the CNPq Authorisation for Scientific Expeditions must also be obtained, through the Brazilian partner institution, before access or shipment is registered in SisGen.

Access registration should be completed prior to shipment, requesting any intellectual property rights, disseminating results (final or partial) in scientific or other means of communication, commercialisation of an intermediate product, or when economic exploitation of finished products or reproductive materials occurs. Access does not have to be registered prior to sending samples for services provided abroad.

Some access activities may be carried out only with the prior authorisation from national authorities:

- access to GH or ATK in areas indispensable to national security – the National Defence Council decides and grants the authorisation;

- access to GH or ATK within Brazilian's territorial waters, continental shelf or exclusive economic zone – the Maritime Authority decides and grants the authorisation.

This prior authorisation is applicable when the user is:

- a national legal person, whose controlling shareholders or partners are foreign natural or legal persons;
- a national institution of scientific and technological research, public or private, associated with legal persons headquartered abroad;
- a Brazilian natural person associated, funded or contracted by a legal person headquartered abroad.

Sending and Shipment

The law differentiates 'shipment' from 'sending'.

Sample Shipment: transfer of GH sample to an institution located outside the country for the purpose of access, in which responsibility for the sample is transferred to the recipient.

Sample Sending: sending of sample that contains GH for services provided abroad, as part of research or technological development, in which the responsibility for the sample is held by the person who conducts the access in Brazil.

Shipment involves a change in responsibility, e.g. when a Brazilian researcher ships a sample to an EU researcher for utilisation in an EU project. According to Article 25 of Decree 8.772, shipment abroad must be registered in cases where access to GH is conducted by a legal person located abroad in association with a Brazilian institution (public or private), or by a Brazilian natural or legal person (public or private) located abroad. Shipment must be registered on SisGen prior to the shipment event.

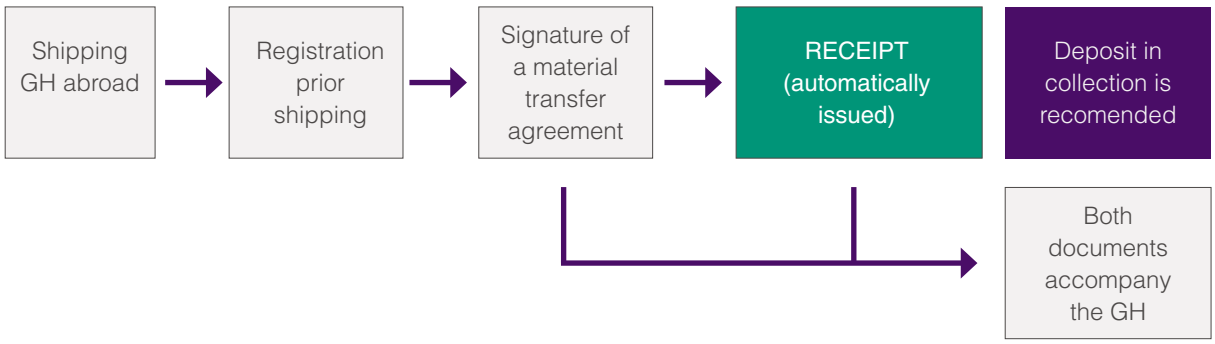
The international shipment of GH samples also requires the signing of a material transfer agreement (MTA). This MTA formalises the shipment of GH samples accessed or available for access and shall contain (Decree 8.772 – Art. 25, §1):

- identification of the provider and receiving institution;
- GH information to the closest

taxonomic level possible and the origin of the samples;

- access activities to be conducted abroad, including objectives, intended uses and application sector of the research project or technological development;
- the obligation to comply with the requirements of Law 13.123;
- information about ATK access, when applicable;
- mandatory clauses stating that:
    - Brazil is the competent jurisdiction;
    - the MTA should be interpreted in accordance with Brazilian laws;
    - the recipient institution will not be considered the GH provider;
    - the recipient institution must require the signing of an MTA with third parties with the obligation of compliance with the Law 13.123 requirements, including Brazil as the competent jurisdiction;
    - the authorisation or the prohibition to transfer the sample by the recipient institution to third parties.

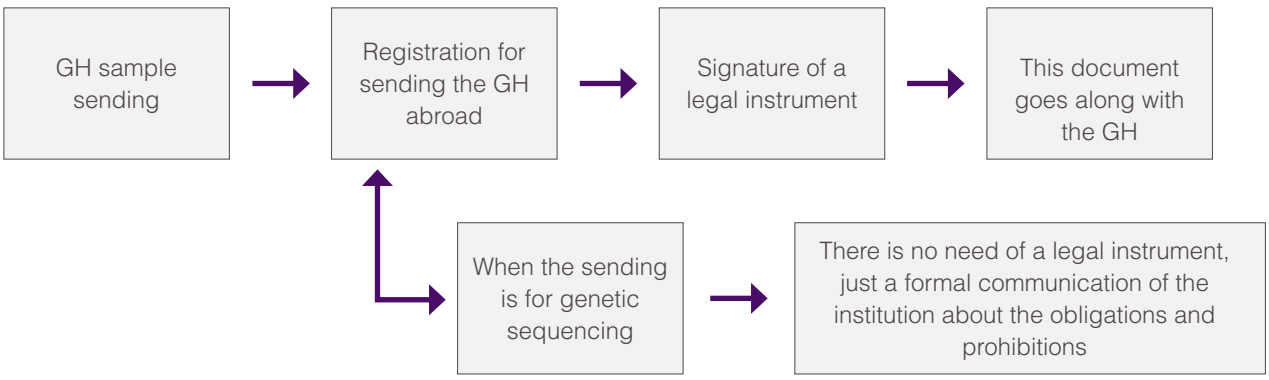
Figure 3: Procedure for complying with the Brazilian legislation regarding shipping GH abroad.



Sending involves no change in responsibility, e.g. when a Brazilian user sends a sample abroad to a lab to be sequenced as part of a Brazilian research project. Sample sending registration shall be carried out within the time limits set for the access registration, and can be done before or after sending the genetic heritage abroad. According to Decree 8.772 (Art. 24), 'services provided abroad' are tests or specialized technical activities performed by the institution collaborating with the Brazilian institution responsible for access or hired by it. Except for genetic sequencing, a legal instrument needs to be signed by the Brazilian institution responsible for access and its partner or contracted institution, and shall contain:

- information about the GH;
- the description of the technical specialized service object of the provision;
- the obligation to return or destroy the sent samples;
- a deadline for the provision of services with details by activity to be performed;
- clauses prohibiting the partner institution or contracted institution from:
    1. passing on to third parties the GH sample or its genetic information, including substances derived from its metabolism;
    2. using the GH sample or its genetic information for any other purposes than those declared;
    3. economically exploiting the intermediate or finished product or reproductive materials resulting from access;
    4. claiming any kind of intellectual property right.

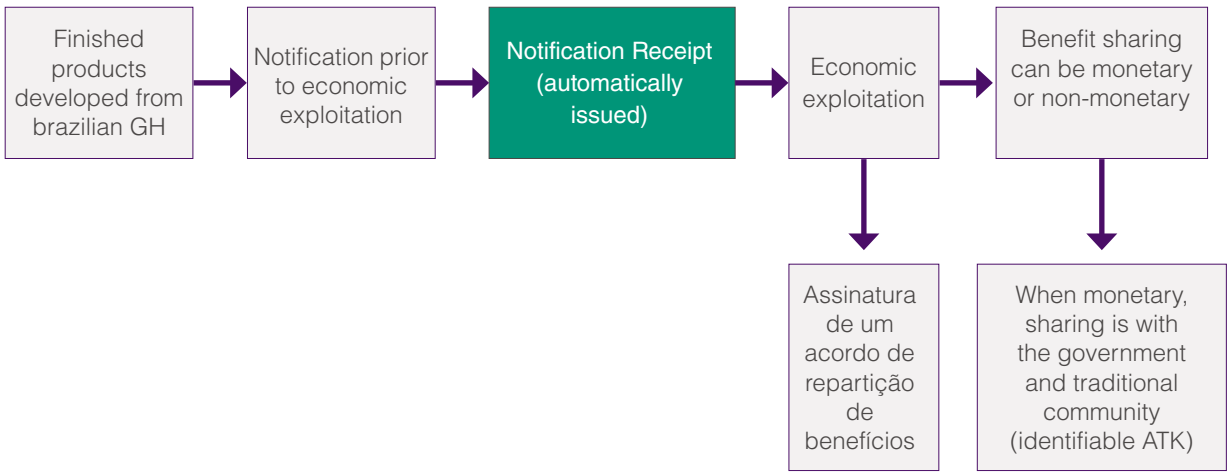
Figure 4: Procedure for complying with the Brazilian legislation regarding sending the GH abroad.



Economic Exploitation

For economic exploitation, the Law requires a prior notification of the finished product or the reproductive material to CGen, and the presentation of a Benefit Sharing Agreement within one year from the time of notification, except in the case of a finished product or reproductive material from access to ATK of identifiable source. In that case, the agreement must be presented at the time of notification. Benefit Sharing Agreements can be replaced by direct deposit at the National Benefit Sharing Fund in the cases of economic exploitation of finished products or reproductive material arising from access to GH or ATK of unidentifiable source, according to the Law 13.123 (Art. 25).

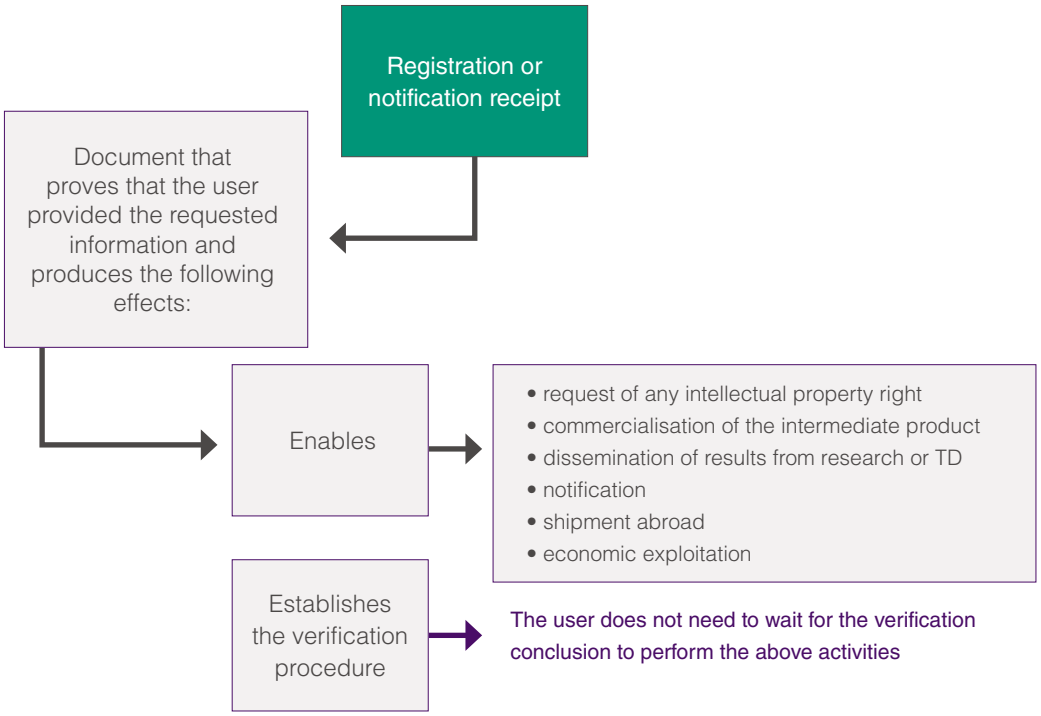
Figure 5: Procedure for complying with the Brazilian legislation regarding economic exploitation.



Verification process

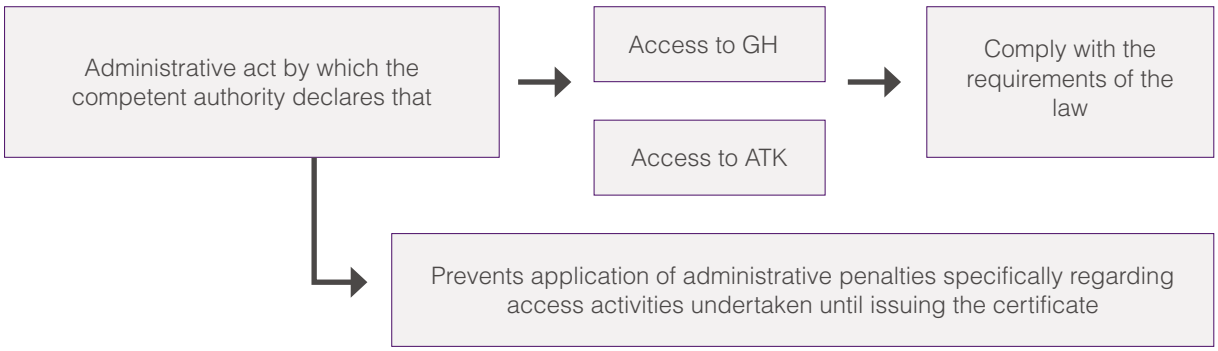
After the SisGen electronic forms for registration and notification are completed, a receipt will be issued automatically. CGen will also conduct a verification procedure on registrations for access, sample shipment, and on notifications. During the verification period, the Executive Secretary of CGen will search for irregularities in registrations or notifications and make the counsellors, members of CGen sectorial chambers and federal agencies responsible for protection of indigenous populations, traditional communities or traditional farmers aware of the registrations and notifications. After this procedure, the user can request a declaration attesting that there were no irregularities in the registration or notification. This declaration is distinct from the Certificate of Access Regularity..

Figure 6: Registration and notification receipt and the verification procedure.6



Upon request of the user, CGen can issue a Certificate of Access Regularity (CAR), which declares compliance with the law.

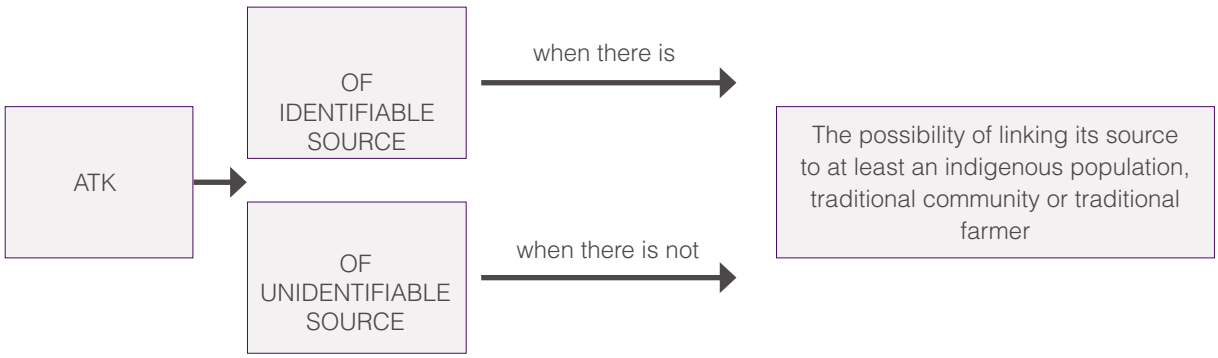
Figure 7: Certificate of Access Regularity.



Associated Traditional Knowledge

The Brazilian legislation protects ATK of indigenous populations, traditional communities or traditional farmers against illicit use and exploitation. The legislation also recognizes the rights of indigenous populations, traditional communities and traditional farmers to participate in decision-making at national level on matters related to the conservation and sustainable use of their ATK. The ATK is considered part of the cultural patrimony and can also be deposited in databases. Any ATK is considered collective, even if held by only one individual of an indigenous population or traditional community.

Figure 8: Associated Traditional Knowledge.



Access to ATK from an identifiable source is conditional upon obtaining Prior Informed Consent (PIC), but access to ATK from an unidentifiable source does not require PIC. Any indigenous population, traditional community or traditional farmer who creates, develops, holds or preserves certain traditional knowledge, is considered an identifiable source of such knowledge. ATK can be recognized in scientific publications, records in registers or databases and cultural inventories.

Benefit Sharing

According to the Brazilian ABS Law, the benefits arising from economic exploitation of finished products or reproductive material originating from access to GH or access to ATK must be shared in a fair and equitable way. Benefit sharing may be monetary and/or non-monetary:

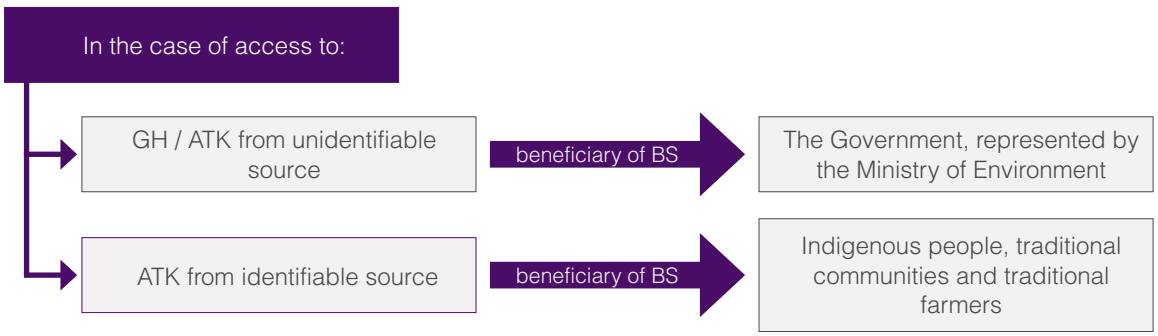
- Monetary: 1% of annual net revenue or up to 0.1% according

to a sectoral agreement. Only the manufacturer of the finished product or the producer of the reproductive material will be subject to benefit-sharing, regardless of who previously performed the access. In the case of monetary benefit-sharing related to access to GH and/or access to ATK of unidentifiable origin, a deposit in the National Fund for Benefit-Sharing (FNRB) is required, rather than a Benefit Sharing Agreement.

- Non-monetary:
  - projects for conservation, sustainable use of biodiversity, protection and maintenance of knowledge, innovations and practices of populations holders of traditional knowledge;
  - technology transfer;
  - availability of the product for public domain, without intellectual property protection;
  - training of human resources on issues related to conservation and sustainable use of GH or ATK;
  - free distribution of products in programs of social interest, among others.

A Benefit Sharing Agreement must be established between the entity that economically exploits the finished product or reproductive material originating from access to GH/ATK and the ATK provider or, in the case of unidentifiable source ATK or access to GH only, the Government.

Figure 9: Beneficiaries of benefit sharing.



The Brazilian ABS Law creates the National Fund for Benefit-Sharing (FNRB). This Fund is linked to the Ministry of Environment, with the aim of valorizing GH/ATK and promoting their use in a sustainable manner. Monetary funds deposited in FNRB arising from access to ATK are used exclusively for the benefit of traditional knowledge holders. Funds deposited in FNRB arising from access to GH obtained from recognised ex situ collections are allocated partially to these collections.

A National Program of Benefit Sharing (PNRB) will be implemented with funds from FNRB, in order to promote:

- conservation of biological diversity;
- recovery, creation and maintenance of ex situ collections that hold GH samples;
- training of human resources associated with the use and conservation of GH and ATK;
- survey and inventory of GH;
- support for the efforts of indigenous populations, traditional communities and traditional farmers towards the sustainable management and the conservation of GH;
- adoption of measures to minimize or eliminate threats to GH;
- other actions related to GH and ATK access and conservation.

Gaps and bridges between Brazilian and EU measures

The project explored the interaction between the two legal systems, identifying areas where they clearly connect and where there are differences that might be problematic if not addressed or recognised.

Terminology

The differing use of terms provides multiple opportunities for confusion, and potential obstacles to mutual comprehension and compliance.

Brazil and European countries employ the critical term ‘access’ (not defined by the CBD or the NP) quite differently: for Brazil, access means ‘research and technological development’, close to the NP’s definition of utilisation, while in the EU Regulation, access is defined as acquisition.

Additionally, the EU regulation applies to ‘genetic resources’ (as defined in the CBD), while Brazilian law applies to broader ‘genetic heritage’. These and other key terms with different

interpretations were noted throughout the project dialogues, and are set out in full in Table 1. Caution is required in all transactions and discussions to ensure that terms are understood..

Tabela 1. Termos empregados em transações de ABS no Brasil e na UE.

Term	Brazil (for access only)	EU (for compliance only)
Access	'Research or technological development carried out on **genetic heritage** sample' May be considered as 'access to the molecule'. Effectively the equivalent of **utilisation** in the EU Regulation. The date of acquisition of the genetic heritage is not relevant. Access (utilisation) is covered after 30 June 2000.	'Acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol'. The EU Regulation covers genetic resources or TK (and not other information) that were acquired from a country that was at the time of acquisition a Party to the NP.
Benefit-sharing (Benefit-sharing agreement)	Under Law 13.123 benefit-sharing is triggered by economic exploitation; only the manufacturer of the finished product or producer of reproductive material is expected to share benefits. The legislation fixes proportions of annual net revenue, which can be negotiated by sectoral agreement (not bilaterally by individual users). Benefit sharing may be non-monetary and is fixed at 75% of the monetary value, by agreement. If the value to be shared is 1% of the annual revenue, the non-monetary benefit will be equivalent to 75% of that value. Additional benefits may be agreed bilaterally between the Brazilian and EU partners, but these are not addressed by the law.	May include monetary or non-monetary, but the EU regulation – although it requires that benefits are fairly and equitably shared on MAT (in accordance with applicable legislation), – does not per se regulate benefit sharing aspects; it requires that MAT(s) have been established if required. Most Europeans would expect benefit-sharing to address monetary and / or non-monetary elements, as appropriate, and would expect benefit-sharing to be established early in discussion between initial research users and providers as this early cooperation tends to generate a high amount of valuable (although typically non-monetary) benefits.

Term	Brazil (for access only)	EU (for compliance only)
Genetic Heritage, Genetic Resources	Genetic heritage: 'genetic information of plant, animal and microbial species or species of other nature, found in situ within the national territory, on the continental shelf, the territorial sea and the exclusive economic zone, including substances derived from the metabolism of these living organisms'. The Brazilian Law includes derivatives and information.	Uses CBD definition of genetic resources: 'material of plant, animal, microbial or other origin containing functional units of heredity, of actual or potential value' The EU Regulation uses the CBD definition of genetic resources. The scope only covers access (=acquisition) to derivatives when they are contained within a genetic resource. Digital data obtained from gene sequences, which are frequently stored in publicly available databases, are currently considered outside the scope.
Mutually Agreed Terms	Decree 8.772/2016 lays down what must be included in the MAT, including a requirement to comply with Law 13.123/2015. Financial arrangements are set out in a separate Benefit-Sharing Agreement. There may be an additional bilateral MAT between Brazilian and EU partners, but this is not covered by legislation.	The Regulation requires that MAT have been agreed if required by the provider, but does not address the contents. Most Europeans would expect the MAT to address all terms, not only those laid down in the Brazilian Decree.
Prior Informed Consent	Used only in the context of TK and indigenous people, traditional communities and traditional farmers.	Applies to access to GR and ATK, according to particular provider country legislation/ regulatory requirements.

Term	Brazil (for access only)	EU (for compliance only)
Sending (samples of genetic heritage	Transfer of the material to a third party outside Brazil for access with no change in responsibility, e.g. to a sequencing facility overseas or to an EU partner who is only carrying out analysis for the Brazilian partner and will return or destroy the material.	'Sending' and 'shipping' seem to be synonymous in EU and are not legally defined in the EU Regulations.
Shipping	Transfer of the material to a third party outside Brazil for access with a simultaneous transfer in responsibility for the material, either permanently or temporarily (e.g. for the recipient's research). Also applies to a Brazil-based Brazilian researcher who takes the GH out of Brazil temporarily to access it elsewhere.	'Sending' and 'shipping' seems to be synonymous in EU and are not legally defined in the EU regulations.
Utilisation	Not used. Instead the legislation refers to 'Research' (not leading to an economic product) and 'technological development' (directed at producing an economic product).	'Utilisation of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention (definition from Nagoya Protocol).

Coordination of monitoring stages

As discussed below, monitoring of ABS activities allows provider countries to know when key steps in the value chain have taken place (e.g. utilisation, economic exploitation).

The project sought to understand how closely the monitoring trigger points under Brazilian access and European compliance legislation coincide; the points are compared in Table 2. In the Brasília discussions it was believed that the point at which notification was required by Brazil in the context of economic exploitation (prior notification of the finished product or the reproductive material) was comparable to that required for a Declaration of Due Diligence under article 7(2) by the EU Regulation (at the stage of final development of a product), however further clarification is needed. Such clarification will require further discussion with authorities in the EU and Brazil.

Table 2. Comparison of the monitoring points at which registration/notification of use is required by Brazil and Declarations of Due Diligence are required under the EU Regulation

Monitoring points	Brazilian Law	EU Regulation
Utilisation	**Access** (=utilisation) **registration** may be made at any point during research and technological development. Access registration is required prior to • Request of any intellectual property right • Commercialisation of any intermediate product • Release of results, final or partial, in scientific or communication circles • Notification of finished product or reproductive material developed as a result of the access (=utilisation) **Sample sending registration** is required when sending material for services provided abroad, but sending registration can take place before or after access registration **Shipment registration** is required prior to shipment abroad	• At the stage of research involving utilisation of GR, if subject to private or public funding in the form of a grant to be made after the first instalment of funding has been received and all the GR and ATK that are utilised in the funded research have been obtained, but no later than at the time of the final report, or in absence of such report, at the project end
Commercialisation and pre-commercialisation	Notification of the finished product or the reproductive material is required prior to economic exploitation.	Prior to the first of the following events occurring: a) When market approval is sought b) When notification is required* c) When placing product on a market d) When result of utilisation is sold or transferred for the purpose of (a), (b) or (c) e) When utilisation ended in EU and its outcome sold or transferred outside of EU

*Under EU Regulations, Notification is required prior to placing some products (e.g. cosmetics) on the market in the EU; this is not to be confused with the Notification system under Brazilian ABS law..

Benefit-sharing responsibilities

Under the Brazilian law, benefit-sharing arrangements are triggered by economic exploitation (see Table 1). A Benefit Sharing Agreement (BSA) is to be completed within one year after prior notification of the finished product to CGen, unless ATK of identifiable source is involved, in which case the notification and agreement must be at the same time. Benefit-sharing resulting from access to GH or ATK of unidentifiable source does not require a BSA; instead, financial benefits can be deposited directly at the National Benefit Sharing Fund. This arrangement is a novel approach, different from the usual expectations and practices. The working groups in the London meeting discussed the responsibilities and timing involved. Business representatives raised the possibility that a product might be developed with GH from many sources (and thus with multiple agreements), which would pose challenges.

The BSA requirements allow for the possibility of non-monetary benefits in addition to monetary benefits, offsetting the latter. The project group recommended that Brazilian stakeholders should consider developing methodologies to quantify the value attached to non-monetary benefits, which could assist negotiations with commercial partners. The law sets out no requirements for benefit-sharing at earlier stages and transactions. Benefits arising from collaboration and non-commercial utilisation should be recognised and shared via collaborative research agreements and material transfer agreements.

Both workshops considered how the laws address non-users (non-utilisers) in the supply chain. The Brazilian law does not cover the supply chain. Under the Brazilian law, the supplier of raw materials is not liable for benefit-sharing for a finished product developed by their customer.

The EU Regulation does not address transfer between non-users in the supply chain. However, under the EU Regulation, users in the EU will be checked upon compliance with their due diligence obligation (applicable to all in the value chain) though they do not need to submit a DDD for each shift and change in the chain; this will in practice place a requirement on users to source GR only from a supply chain that supplies legally-accessed GR with the information required by users for legal compliance.

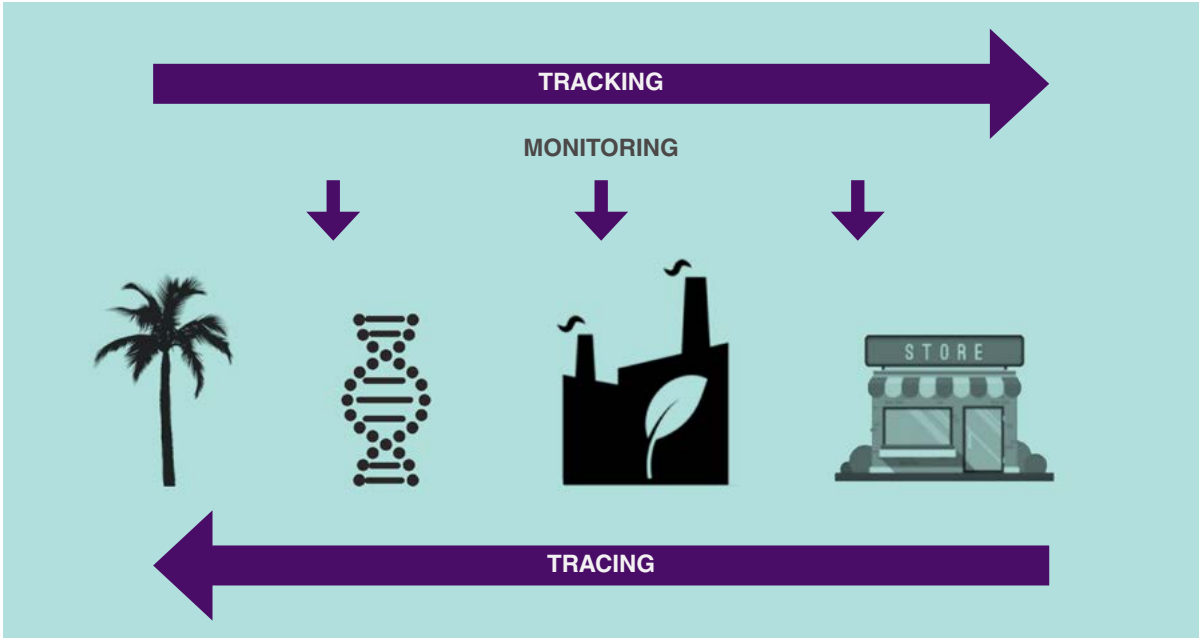
Monitoring, tracking and tracing

These terms are central to the project, and their different implications are important to recognise.

- **Tracking:** Where is the object now, and where has it been?
- **Tracing:** Where did the object come from, and what conditions apply to my custody and use of it?
- **Monitoring:** What has happened to the object?

Each of these processes may rely on recording only specific events, e.g. third party transfer, subsampling to derive multiple entities, separation of associated organisms, utilisation, derivative extraction, commercialisation of results.

Figure 10: Monitoring, tracking and tracing.



Generally speaking, providers are likely to prefer tracking to tracing; tracking potentially provides more complete information (and control, via reports and/or notifications) about how an object is being used and where it is subdivided and transferred along chains of custody, utilisation and value - especially as objects move between institutions/ organisations. Users are interested in the movements of an object within their institution and their own responsibilities for it, but less interested in the object's (or subsamples') movements elsewhere, out of their custody. Under the EU ABS Regulation, they are however obliged to transfer the set of required information to the subsequent user in the value chain, including the source from which they directly obtained the GR or TK. They have not necessarily developed cost-effective systems to report details of uses and transfer, but are likely to be able to trace back to how they received the object and to keep records of the terms that apply.

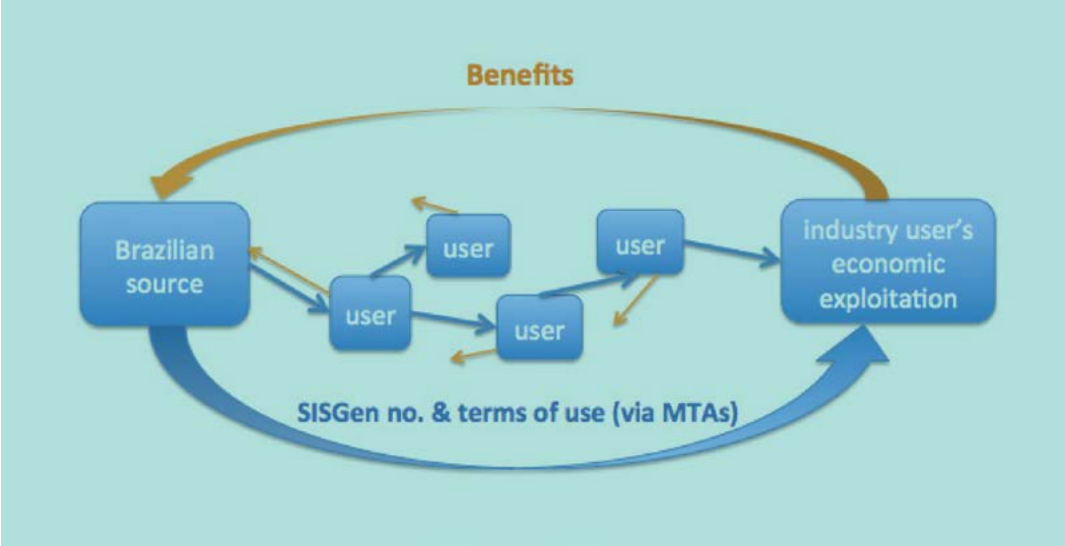
In practice, any continuous system of real-time recording of where an object is and what is happening to it may be costly to manage and may deliver an unmanageable amount of information. Monitoring does not require a continuous system; in both Brazilian and EU systems, certain key stages are identified. Some of the events mentioned above, in particular utilisation and upcoming commercialisation, are triggers in both Brazilian and EU legislation (in both cases subject to modifiers) (Table 2).

Purpose of monitoring genetic heritage

The Brasília workshop helped to clarify that the purpose of monitoring under the new Brazilian law is to ensure keeping of information about Brazilian origin and the terms of use associated with the genetic heritage as it is utilised and transferred, so that benefit-sharing takes place at the end of technological development.

The goal is traceability back from the end point to the origin, not tracking of each and every movement (Fig. 11). With this understanding, the project's focus shifted away from the precise details of tracking mechanisms (e.g. how identifiers are assigned and whether they must be globally unique and persistent) and towards the documentation that will accompany material: registration receipt numbers, which could be transferred to IRCCs to allow full transparency, and Material Transfer Agreements (MTAs).

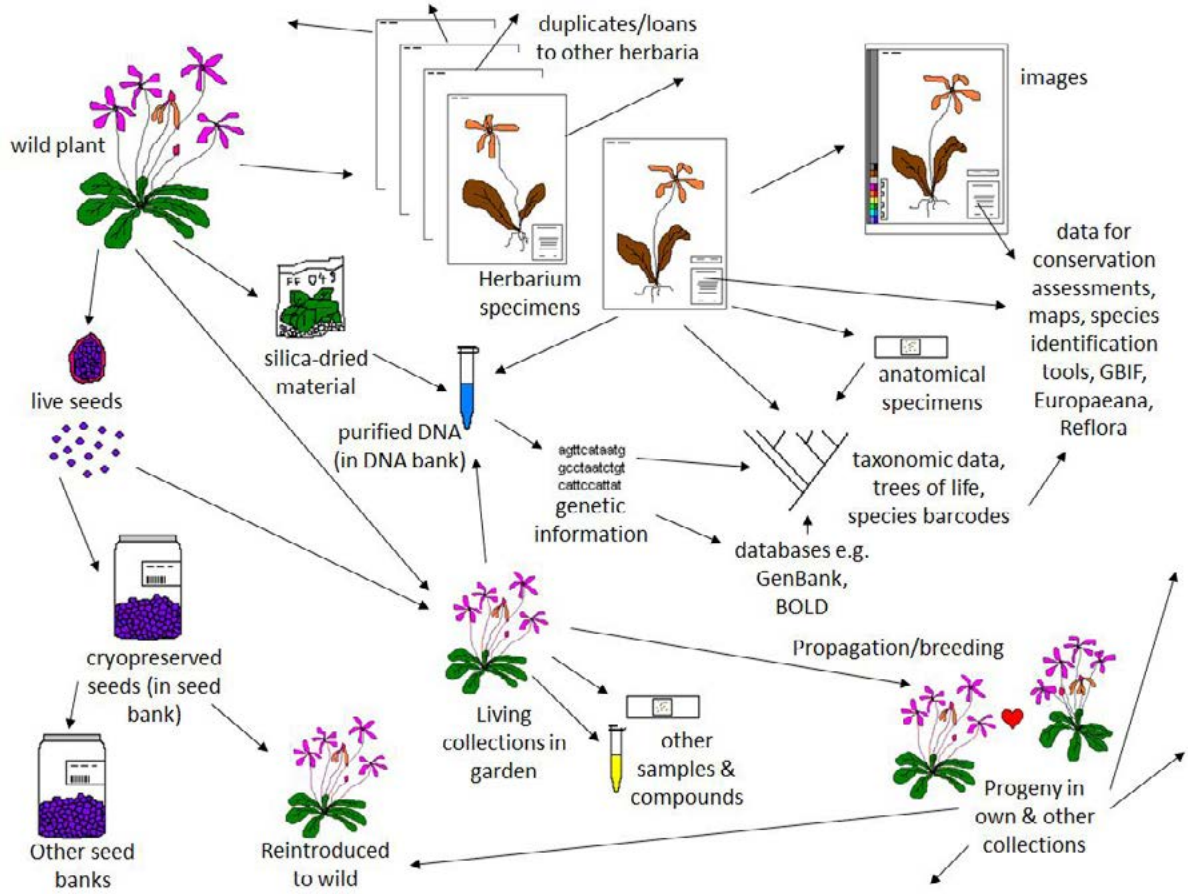
Figure. 11: Traceability, from the endpoint, of Brazilian origin and terms of use (transferred along a chain of custody and utilisation via the SisGen shipment registration receipt numbers and Material Transfer Agreements (MTAs)), to enable the sharing of benefits generated from economic exploitation. Other benefits generated along the utilisation chain (e.g. fieldwork opportunities, technical exchanges and scientific publications) are not captured by the benefit-sharing agreements required in connection with economic exploitation, but may be recognised and shared via the terms of collaboration agreements and MTAs.



Sectoral tracking/tracing systems

The project explored the tracking/tracing systems and best practices of a wide range of non-commercial and commercial sectors that utilise genetic resources, including microbial collections, museums and botanic gardens, the seed industry, pharmaceutical industry, and industrial biotechnology. Unsurprisingly, these sectors vary widely in their practices and the level of detail they are prepared to share, due to their different uses and associated risks.

Figure 12. Life of a specimen: some of the potential transformations and pathways of a specimen, its derivatives and progeny in a botanic garden that conducts non-commercial research and conservation activities. (Illustration © Kate Davis)



Of the groups described, the microbial collections community have the most highly developed and coordinated tracking options for GR, such as TRUST and MIRRI models (see 'Best practices to manage responsibilities and promote traceability,' below). TRUST uses a code of conduct, globally unique identifiers (based on electronic markers), Material Transfer Agreements, and coordinates information sharing via the Global Catalogue of Microorganisms (GCM), which merges collections' catalogues and links them to published data.

Museums and botanic gardens are much less likely than microbial collections to utilise or supply GR for commercial purposes; the GR are arguably thus at lower risk of misuse, although they may

take complex internal journeys (Fig. 12). Although institutions are capable of some internal tracking and tracing using locally unique identifiers, and curating permits and MTAs, the linkages between (a) providers, (b) permits/MTAs, (c) GR or ATK and (d) research results are not always perfectly maintained. However, practices are adjusting; for example, the International Plant Exchange Network has developed a unique identifier that enables the tracing of botanic gardens' living plant collections back to their countries of origin and alerts gardens to any restrictions. ABS functionality is being added to many collections management systems to capture information on PIC and MAT and enable tracing. Collections communities have developed various ABS policy measures that promulgate desired outcomes while allowing for different institutional implementation, such as the CETAF, GGBN and IPEN codes of conduct and the Principles on ABS, and MTAs to ensure that material is not supplied for commercial uses unless consent is obtained from countries of origin.

Tracking and tracing of source materials and products is essential for any company, although for reasons of competitive advantage or legal concern, the details of such systems are not generally shared. GR and associated information are kept linked internally via various locally unique identifiers, using means that vary from sophisticated laboratory information management systems to breeders' notebooks. Several pharmaceutical and biotechnology companies have developed strong ABS principles and policies to ensure that they have legal certainty for all the GR that they research and develop, and some sectoral best practices are available. In the seed industry, ABS best practices have not yet been disseminated, though recommendations are being developed. Plant breeders face significant ABS challenges, as the development of new varieties involves the selection and combining of traits from many plants of different origins, so the more complex or restrictive the terms on material, the more difficult it is to track, manage and comply with the combination of terms that applies to a final product.

Use of unique identifiers to enable traceability

The project explored the role of unique identifiers in the legislative measures and in sectoral systems. Unique identifiers are important tools to support a global ABS system, as they help to link providers, genetic resources and results. The project recognised the distinctions between identifiers that are applied to a) documented permissions in the workflow, such as for acquisition, utilisation or transfer to third parties; b) genetic resources and their derivatives

and products; and c) results such as publications. In practice, identifiers may be locally unique (used internally by a particular organisation) or persistent and globally unique. Different users employ different formats of unique identifier, from the computer-generated UUID (Universally Unique Identifier, a 128-bit number) and GUID (Globally Unique Identifier) to human-readable numbers, such as formed by a country prefix followed by a date and a serial number for records created on that date, or the International Plant Exchange Number, which encodes country of origin, garden that first receives material in the IPEN system, any restrictions and the first garden's accession number.

their use. Unique identifiers may be applied in different ways, for example:

By users to multiple resources.

For example, the Natural History Museum (London) applies a UUID to 'Acquisitions,' which may comprise many different specimens or samples provided together from a single source. These may include representatives of many species that will subsequently be stored in different localities in the collections. The database provides the means to trace the original Acquisition record, to which a scan of the permit is attached. The system manages tracing but is less effective at tracking. Culture collections may require a depositor's identifier with acquisitions, which may also be multiple species.

By users to individual strains or specimens.

Under the MIRRI Best Practices, microbial Biological Resource Centres (mBRCs) apply a unique strain identifier to each strain held. This identifier is transmitted between mBRCs. Similarly, NHM may apply additional identifiers to individual specimens or genetic samples, which will be associated within the database to the initial Acquisition record. Such records can be exposed externally in databases or publications with the addition of a unique institutional prefix.

By users to manage developments in the value chain and manage ABS and contract compliance

In addition to applying unique identifiers to strains or cultures, companies such as Novozymes may have an in-house system to keep track of process, with each step in the development having its own unique identifier that links both back and forth in the development chain.

To facilitate wider communication between users and providers.

The online catalogue of microbial strains maintained by the Global Catalogue of Microorganisms at the WFCC-MIRCEN World Data Centre for Microorganisms can use strain identifiers provided by mBRCs, linked to the unique identifier for the mBRC itself, to provide information to any user, including location of strains, appearance of strains in publications, use in patents, and sequence information.

To identify permits and other documents providing legal certainty or contractual requirements.

In Brazil, registration is required to legitimise access (defined as research or technological development), sample sending and shipment. Shipment registration will generate an MTA, and in due course a notification may be made for economic exploitation, and a Certificate of Access Regularity might be provided by the Competent Authority at the request of the user. The key number, which should be transmitted through all the other documents, is that of the original SisGen-generated registration receipt, which is possibly the document to be used to generate an IRCC, via publication on the ABS Clearing House. While this number will be entered onto the IRCC, it cannot be the IRCC number itself (which is generated automatically by the ABS-CH), but it could be used in the IRCC title to facilitate location. Application of a single permit number facilitates search of publicly available content (e.g. databases, publications, permits, research reports etc.) for its mention, and thus facilitates a cheap semi-automated monitoring system. Free software can be used to add the facility of QR codes, which can be applied to specimens or samples to help users to rapidly discover permit conditions, and downloaded onto mobile devices to facilitate field checking of permits by police and environmental management agencies.

One proposal coming from the London workshop was that permits from different government agencies could be issued through a single web-based portal. This could be very cost-effective in delivery, not inhibit individual requirements of different agencies, and make it far simpler for users in a variety of sectors to comply with the relevant regulations. The recommendation was not addressed to specific Brazilian agencies, but rather was a general point.

While stakeholders may apply unique identifiers, the identifiers and the

information to which they are linked are not necessarily openly available. Without prejudice to reporting requirements and contractual agreements, commercial entities will necessarily keep their activities confidential for business reasons, and research bodies may limit open access to data under study.

Characteristics of a workable traceability system

To achieve goal of traceability from economic exploitation back to Brazilian origin, project participants agreed on core components:

- A unique and persistent identifier to link Brazilian origin and terms of use to genetic heritage. This identifier is derived most effectively from the relevant official Brazilian documents. It may also link to eventual IRCC number, as described above;
- A system including a database(s) to link this identifier to samples/ individuals/isolates from genetic heritage so that when the final product is developed, the responsibility for benefit-sharing is known;
- Flexibility between different sectors; GUIDs for genetic resources and their derivatives and products would be ideal for the monitoring of compliance by strengthening the link between the GUID for access and any downstream results or products, but such GUIDs are not yet used by all sectors. However, internally unique identifiers can provide the required functionality, can be exposed externally via the addition of a unique institutional prefix, and can be found using appropriate search techniques.

Project participants recommended that the Brazilian unique identifier (first bullet point above) should be associated with all official documents in Brazil (perhaps with an appropriate prefix or suffix to denote the type of document) and the EU; used by researchers and developers in their databases; and used in reports to regulators, publications (including on databases such as GenBank and BOLD), patents or when sharing results. The Brazilian unique identifier could also be made globally unique, perhaps by the addition of a prefix denoting the Country (ISO 3166-1).

Model contractual clauses: The Brazilian MTA

The use of Material Transfer Agreements (MTAs) features strongly across sectoral ABS best practices around the world. The Brazilian MTA plays a key role in Brazilian-EU cooperation, traceability and compliance. The Brazilian law requires the MTA for shipment, to convey the terms of use and ABS identifier for a Brazilian GH sample as it is transferred from a Brazilian entity to a recipient and, via subsequent MTAs at every transfer (where onward transfer is allowed), to subsequent recipients. The project group agreed that the MTA should therefore be understandable and easy to manage and it should avoid hindering work that might lead to benefits for Brazil. It is in the interest of users further down the supply and value chains to require those further up the supply chain to make available information required to provide legal and contractual certainty.

The Brazilian MTA is required by the Decree to hold certain minimum information, including a requirement to comply with Brazilian Law 13.123, but other content can be developed between suppliers and recipients. The EU ABS Regulation foresees also that certain information 'travels' with the GR along the value chain, including information on place of access and MAT.

CGen will be developing a model, and intends to keep a database of sectoral MTAs, which could effectively become an online repository of model clauses. The mandatory terms could be considered as 'viral,' travelling through the whole chain of custody. The model should also contain options regarding confidentiality.

The development of standard clauses is helpful for user compliance: standard clauses are much more easily recognised by upstream and downstream users and transmitted between institutional systems. In particular it is useful to transmit, via certain 'lowest common denominator' clauses across sectors, information such as whether if material can be loaned or not; if it can be supplied or not; if it can be transferred but reporting is needed before commercial research is undertaken; if material can be sequenced or not; if it can be destructively sampled or not. However, it should be noted that the more controlled the contractual obligations are, the less productive the collaborations may be.

The Brasília working group made recommendations for the development

of the MTA, including that a single MTA should accompany a shipment, to avoid confusion regarding the tracking of multiple MTAs issued by different agencies; standard clauses should be developed where possible for the non-mandatory content, appropriate to the sectoral use of genetic heritage; the MTA should include the unique identifier(s) of the genetic heritage, for tracking/tracing; the MTA should include a glossary (e.g. for 'genetic heritage' and 'access') so that recipients better understand their obligations; and the MTA could contain clause-by-clause translation, at least into English. The group also suggested that ways should be explored to make model clauses available electronically/online and to generate MTAs via an electronic/online system.

Best practices to manage responsibilities and support traceability

ABS is a complex issue and users do not all understand how to manage their responsibilities. Best practices and other voluntary compliance tools such as codes of conduct, guidelines and standards can help to minimise legal and reputational risks and ensure compliance (including with contractual terms). They can describe what should be achieved, and do not need to be prescriptive; they can help to adapt behaviour to a rigid regulation. They have been shown to be very helpful in a number of different sectors in the EU, such as the TRUST system[16] and MIRRI[17] and OECD best practices[18] for microbial collections, the CETAF[19] and GGBN[20] Codes of Conduct and Best Practices for taxonomic institutions and the Principles on ABS and IPEN for botanic gardens[21].

Best practices have been given a role in the implementation of the Nagoya Protocol and the EU Regulation and their development is actively encouraged. Project participants shared examples of how best practices can also help to address the identified gaps in the Brazilian and EU systems, including by improving supply chain ethics and traceability and by raising the awareness of users sourcing from a supply chain, e.g. via the Ethical BioTrade Standard[22].

The group agreed that best practices are tools that can be recognised by government(s) but they need to grow from the needs and systems of sectors and sectoral networks. A sense of

16. http://bccm.belspo.be/projects/trust
17. www.mirri.org/fileadmin/mirri/media/Dokumente/generalDocs/MIRRI_ABS_Manual_web.pdf
18. www.oecd.org/sti/biotech/38777417.pdf
19. www.cetaf.org/
20. www.ggbn.org/
21. www.bgci.org/policy/abs/
22. http://ethicalbiotrade.org/verification/ethical-biotrade-standard/

appropriateness and ownership will improve buy-in, so Brazilian sectors and networks may prefer to develop their own measures. However, existing best practices can be used as a basis for development and adaptation (their core elements tend to be very similar), so where they can be used without modification, it might be wise to avoid an over-proliferation of best practices.

The project's recommendations include that Brazilian scientists should, in consultation with CGEN, review a range of existing sectoral best practices and guidance from relevant agencies, and develop or adopt best practices that fit the ways they work, to facilitate traceability to origin and compliance with terms of use.

Raising awareness, sharing information and building skills

Currently many stakeholders in Brazil and the EU know little about the new ABS measures and how they work. The project activities themselves generate a first step, as participants share information with their institutions, societies and companies. The group recommended ideas to encourage information exchange, awareness raising and training, including dissemination and translation (at least into English) of Law 13.123 and Decree 8.772, MTA clauses, explanatory guides, factsheets and other guidance tools, to help Brazilian and foreign users understand their responsibilities.

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