Monitoring requirements of the Nagoya Protocol and new EU and Brazilian legislation, and existing sectoral workflows for tracking ABS information: a preliminary analysis

Background paper for the Brazil ABS Workshop

7-10 June 2016, Brasília

Kate Davis and Paulo Holanda
Project Consultants

Table of Contents

Executive summary

This workshop will explore the frameworks for the monitoring of genetic resources (GR) under the Nagoya Protocol (NP) and new legal and administrative measures in the European Union (EU) and Brazil, and examine the current mechanisms for tracking and monitoring GR that are used by a range of sectors. The aim is to build and strengthen bridges between Brazilian and European researchers, enterprises and governments. The bridges will be sounder if we can better understand the linkages between existing structures, identify the gaps and problems that are obstructing understanding and cooperation, and suggest practical solutions. This paper provides background detail on the legal framework and current sectoral tracking practices.

Legal framework

The Nagoya Protocol (NP) sets out elements for the monitoring of utilisation of GR and associated traditional knowledge (ATK) for implementation by national and regional governments. Brazil's Law 13.123 and the EU Regulation 511/2014 are now in force, although comprehensive systems for implementation between different Brazilian agencies and across all EU Member States are not yet finalised. Those that utilise genetic resources ('users') must now analyse sectoral and individual practices to ensure their tracking capabilities are sufficient to meet their new obligations, as genetic resources (GR) circulate within and between collections, organisations and companies along chains of custody, utilisation and value. We contrast monitoring of stages of GR utilisation to assess the functioning of ABS systems, tracking of every movement of a GR, and tracking or tracing back to the origin of GR and keeping providers' terms linked with GR.

The NP establishes the Access and Benefit-Sharing Clearing House (ABS-CH), an information-sharing mechanism that plays a central role in the global monitoring of ABS actions. For those NP Parties that regulate access and benefit-sharing, the ABS-CH accepts information from national access permits and 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 agreed terms (MAT), although these data may not be made available on the ABS-CH where 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. IRCCs may provide much of that information – and to pass it to the ABS-CH, as well as to the provider of PIC and the person to whom PIC was granted, as appropriate. 'Access' is not defined in the Nagoya Protocol.

The EU Regulation 511/2014 establishes a system to monitor GR utilisation. Users are obliged to exercise 'due diligence' as they access (*acquire*) GR/ATK for utilisation from NP Parties that regulate access, with PIC and MAT as necessary, and they must seek, keep and transfer such ABS information to subsequent users. Compliance is checked at two key stages at which users must provide 'due diligence declarations' (DDDs) to the competent authority in their Member State: (1) the stage of research funding and (2) the stage of final

development of a product. The competent authorities will report information from DDDs to the ABS-CH via checkpoint communiqués. EU-registered collections must be able to track/monitor their supply of GR/ATK to third parties for utilisation, and their ability to do so will be verified regularly by Member States, but information on exchanges and sample transfers is not reported. EU-recognised best practices provide guidance developed at a sectoral level for meeting the obligations for 'due diligence.' EU Member States are now establishing the national laws and structures necessary for implementation.

The Brazilian ABS Law 13.123 (2015) replaces previous ABS legislation and establishes a new registration system. The Genetic Heritage Management Council (CGen) has an important role managing ABS information and will maintain the online system SISGen. Only Brazilian natural and legal persons can use the system. Users will register using SISGen at any time while accessing (*conducting research and development on*) Brazilian genetic heritage (GH) or ATK. Users must also use SISGen to register sending samples abroad for contracted services, but this may be done before access is registered. Access registration should be done *prior* to shipping samples abroad for access, and a separate SISGen shipment registration is required. Access must also have been registered prior to requesting intellectual property rights, disseminating results, and when economic exploitation of finished products or reproductive materials occurs; in this last case, a notification on SISGen is additionally required. International shipment for access requires an MTA in addition to registration, and economic exploitation requires a benefit-sharing agreement. When foreign institutions/organisations are involved, access in certain situations requires prior authorisation from the National Defence Council (in areas indispensable to national security) or the Maritime Authority (in Brazilian marine areas). SISGen will issue a receipt after registration (for access and shipment) and notification (for finished products/reproductive materials). 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 genetic heritage (GH) and ATK, but (like the EU measures) they do not constitute a detailed tracking system.

We note certain gaps and bridges between the EU and Brazilian processes. The biggest gap is that the EU Regulation will not apply to Brazilian GR until Brazil ratifies the Nagoya Protocol. Some terms and concepts differ quite significantly; for example the EU and Brazil define 'access' differently, and the EU regulation concerns genetic resources while the Brazilian law concerns 'genetic heritage', a broader concept that includes information and derivatives. The EU DDD1 is similar in function to the SISGen access registration, and DDD2 is similar to the SISGen notification. However, no DDD1 is required for internally funded utilisation projects. No DDD (or due diligence at all) is required when an EU non-user supplies GR to another non-user along a supply chain, or when an EU non-user supplies GR to a user outside the EU. No DDD is required for the utilisation of derivatives, unless derivatives are in the GR that is accessed. EU users are only required to keep the ABS information for 20 years after the end of the utilisation.

This paper also describes the other agencies and processes that are involved when GH/ATK are transferred within Brazil and abroad, regarding collection, transport, biosurveillance for health and agriculture, CITES, border crossings and postal systems. ABS aside, the cumulative requirements of multiple processes involving multiple agencies present a substantial obstacle to research and industry partnerships and benefit-sharing from economic exploitation. By seeking opportunities to share information between agencies' systems and help users to navigate the requirements, some the costs of and impediments to international cooperation could be reduced and removed.

Sectoral tracking systems

This paper then describes the tracking systems and available best practices of several *ex situ* collection communities (microbial collections, museums and botanic gardens) and several commercial sectors (seed industry, pharmaceutical industry, industrial biotechnology industry). The sectors vary widely in their practices and their representatives' willingness to release or describe details, due to their different uses and associated risks.

Of the groups described, the microbial collections have the most highly developed and coordinated tracking options for GR, such as TRUST and MIRRI models. 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, and the GR are arguably thus at lower risk of misuse. Although institutions are capable of some internal tracking using locally unique identifiers, and curating permits and MTAs, the linkages between providers, permits/MTAs, GR and research results are not always maintained. The International Plant Exchange Network has developed a trackable unique identifier that links the first three for botanic gardens' living collections, if not the fourth; ABS functionality is being added to many collections management systems to link all four. These 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 permitted. Not all collections are using them yet (very few in Brazil), but the compliance requirements from the EU Regulation and other post-Nagoya laws will likely widen the reach and hasten the uptake of ABS best practice tools.

Tracking of source materials and products is essential for any company, but it has been much more difficult to obtain detailed or diverse information on the tracking systems of commercial sectors. 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. Some 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 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.

Traceability and verification of resources, products and documentation along the chain of custody are increasingly important concepts that are being addressed outside ABS by range of sectors. This paper mentions some of the different systems and methods.

Preliminary analysis

Our preliminary analysis notes that tracking mechanisms are used across all sectors but vary greatly. Other than those microbial collections that are implementing TRUST/MIRRI models using globally unique identifiers (GUIDs), sectors use a range of locally unique identifiers. Although it would be ideal to apply persistent unique identifiers or GUIDs to GR, that is unlikely to be achievable any time soon, and would require global coordination of collections and companies and also other GR users such as university research labs (not considered here), and major financial and technical support. However, the IRCC and trackable documents (e.g. Brazil's proposed CAR) offer persistent identifiers for the ABS terms, at least, which will facilitate the linking of such terms to GR in the sectoral systems. Users must handle more than access permits, so efforts to make other necessary documents more trackable would be useful. Material Transfer Agreements play an important role in sectoral systems (though they are not universally used).

The actual terms and conditions are important as well, not just their linkage to GR. Providers should consider what types of terms are realistic or constructive as material moves beyond the initial user and further down the chain of custody (which may not be a chain of value). These issues are not the focus of this workshop, but are of practical importance regarding compliance and the generation and sharing of benefits.

Questions that arise for the workshop participants after our analysis include:

- What are the goals of a tracking/monitoring system, and what information is necessary to achieve them?
- What identifiers are needed for ABS monitoring to function?
- What information or mechanisms would help to facilitate exchange between Brazilian and European collections under the Brazilian law and EU Regulation?
- Will/should the Brazilian system allow for risk-based approaches?
- How will relevant information be gathered for the Brazilian registry?
- What is the role of Material Transfer Agreements?

1. INTRODUCTION

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.

The Nagoya Protocol provides a legally binding international framework to achieve the sharing of benefits arising from the utilisation of genetic resources, the third objective of the Convention on Biological Diversity. Countries have the sovereign right to regulate access to genetic resources, but if they choose to regulate, they must set out clear laws or other measures and provide information. Countries where genetic resources are utilised must ensure that users are complying with providers' laws, obtaining Prior Informed Consent (PIC) and establishing Mutually Agreed Terms (MAT) as required by the providers' national legislation. The Protocol establishes a system to enable the monitoring of utilisation of genetic resources.

Recognising the potential benefits that arise from greater academic and commercial exchange between Brazil and the EU, this workshop project seeks to explore how new Brazilian and EU regulatory measures will function together, and what tracking and/or monitoring of utilisation of genetic resources is necessary to comply with them and achieve the Nagoya Protocol's objective of benefit-sharing. Brazilian Law 13.123, in force from 17 Nov 2015, establishes a new access regime, based on a registration process. The European Union Regulation (EU) 511/2014, in force from 12 Oct 2014, establishes a new system for compliance for users in EU Member States, based on due diligence measures.

This paper summarises the key elements of the Nagoya Protocol and the Brazilian and EU laws as they relate to the exchange and utilisation of genetic resources within and between Brazil and the EU. We also identify areas where the laws take different approaches, so that participants can work to find possible solutions to bridge the gaps

The paper then compares systems for tracking and monitoring the utilisation of genetic resources within and between Brazil and the EU to look for those features of systems that are effective, practical and acceptable for providers and users. The results of earlier analyses conducted during the larger EU-Brazil Sectoral Dialogues project on ABS are set out in Annexes 1 and 2. Participants might wish to consider how the earlier recommendations relate to the new laws and practical sectoral information set out in this paper.

Tracking or monitoring?

It is important to recognise from the outset that 'tracking' and 'monitoring' are different concepts, and tracking can itself be subdivided. We need to understand what the desired outcomes are, and how tracking and/or monitoring measures are necessary to achieve them.

As discussed by Eaton and Visser (2007, using the Oxford English Dictionary definitions)[1], , tracking involves following the course or movements of an object or finding the object after a thorough search. Tracking systems involve procedures that follow the flows and uses of GR, from original provision to inclusion in a commercial product, and may include procedures to review and verify specific resources. A tracking system

[1] Eaton D, Visser B. 2007. Transaction Costs of Tracking and Monitoring the Flows of Genetic Resources. In A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows. ABS Series. Gland, Switzerland: IUCN, p. 111-123

may involve the tracking of every transfer, i.e. **tracking the course of an object**, determining its current position, and how it got there via transfers and subsampling (e.g. to tissue samples and DNA extracts, or separation of several GRs associated with each other in an original sample, e.g. symbionts, parasites). Alternatively, a tracking system may guarantee that adequate data are available when needed in individual cases – i.e. enable **tracing back to the origin of the object**, proof of its legal acquisition and the terms of use that apply (e.g. whether it can be transferred to third parties, or sequenced).

Providers are likely to be interested in having the ability to track the course, to receive reports on or notifications of how an object is being used and where it is being subdivided and transferred along chains of custody and value - perhaps 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, less so in the object's (or subsamples') movements elsewhere, when it is out of their custody; 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 track of terms[2].

Monitoring may be described as keeping under observation, so as to regulate, record, or control. Monitoring systems (following Eaton and Visser) may function to inform stakeholders about international exchange and the functioning of the ABS system, answering questions on the effectiveness of ABS agreements, by using data for each transfer or taking a synthetic approach. A monitoring system can provide information on what has happened to the object at key stages, such as (potentially) utilisation, extraction of derivatives, applications for intellectual property rights, commercialisation of results of utilisation. A monitoring system can also produce information that can be used for tracking (such as identifiers for permits and registrations).

The Nagoya Protocol sets up a framework for monitoring utilisation to support compliance, using national checkpoints, internationally-recognised certificates of compliance (IRCC) and the ABS Clearing House as tools. These monitoring tools will enhance transparency about the utilisation of genetic resources, providing data to help governments and stakeholders to assess how the ABS system is functioning. They can also be used as part of tracking (and tracing) processes: the IRCC contains a unique identifier that should facilitate tracking of legal obligations, and checkpoints provide certain information to the ABSCH at several key points along a chain of utilisation, if not at all points of custody and use.

While this group discusses different issues and options, we also need to consider which items need to be tracked or monitored: the genetic resources and associated traditional knowledge, the PIC and MAT that apply to them, the users and/or the results of utilisation?

In this paper we present several tracking and/or monitoring systems that are used by different users of genetic resources across different sectors. We note how they use identifiers, and we also note when they are guided by certain sectoral best practices. Best practices, guidelines, codes of conduct and standards can play an important role in the practical implementation of the Nagoya Protocol, the EU regulation and the Brazilian law, providing a sector-appropriate framework to guide institutions' and companies' own actions.

[2] Thanks are due to C. Lyal for articulating the differing interests of providers and users relating to tracking vs. tracing

2. ABS MONITORING MECHANISMS IN THE NAGOYA PROTOCOL, EU AND BRAZILIAN REGULATIONS

2.1 Nagoya Protocol

2.1.1 Overview

The Nagoya Protocol[3] sets out measures for the monitoring of utilisation of GR, to support compliance with providers' domestic ABS legislation or regulatory requirements. It establishes a trackable internationally-recognised certificate (for Parties that regulate access), checkpoints (at least one to be designated per Party) to collect relevant ABS information from users, and the ABS Clearing House to collect and transmit ABS information, thus increasing transparency for providers and users on the utilisation of GR and ATK.

2.1.2 Checkpoints (Art. 17.1.a)

Each Party is to designate one or more checkpoints to collect or receive relevant information related to **Prior Informed Consent (PIC), source, establishment of Mutually Agreed Terms (MAT) and/or to the utilisation of genetic resources (GR)**. Depending on the nature of the checkpoint, users are required to provide such information to the checkpoint, with consequences for non-compliance. Such information, including from internationally-recognised certificates of compliance (see below) will, without prejudice to the protection of confidential information be provided to relevant national authorities, the Party providing PIC, and to the Access and Benefit-Sharing Clearing House (ABS-CH, see below), as appropriate.

Checkpoints should be relevant to the utilisation of GR or to the collection of relevant information at any stage of research, development, innovation pre-commercialisation or commercialisation.

Countries are designating a range of different checkpoints. Examples include the Federal Agency for Nature Conservation (Germany), the National Measurement & Regulation Office (UK), national environmental agencies (South Africa) and the National Commission Against Biopiracy (Peru).

2.1.3 Internationally-recognised certificates of compliance (IRCC; Art. 17.2-4)

An IRCC is **a permit or its equivalent** issued at the **time of access** as evidence of the **decision to grant PIC and the establishment of MAT**, notified to the ABS-CH, and as required by domestic ABS legislation or regulatory requirements of the Party providing PIC.

The IRCC contains **minimum information** (when not confidential): issuing authority, date of issuance, the provider, **unique identifier of the certificate**, the person or entity to whom PIC was granted, subject-matter or GR covered by the certificate, confirmation that MAT were established, confirmation that PIC was obtained, and information as to whether it covers commercial and/or non-commercial use. The IRCC allows for the adding of additional information on PIC, MAT, subject-matter/GR, specified uses or restrictions and conditions for third party transfer.

Further information to describe the GR might include voucher specimen data, taxonomy and/or geographic coordinates, if known at the time of access. One IRCC may cover a number of different GR. It is important to note that the IRCC and its unique identifier essentially refer to the access event, involving particular PIC and

[3] https://www.cbd.int/abs/text/default.shtml

MAT, provider and user, not necessarily to the individual GR – though the individual GR should always remain linked to the IRCC number, by whatever means necessary.

2.1.4 Access and Benefit-Sharing Clearing House[4] (ABS-CH; Art. 14)

The Nagoya Protocol establishes the ABS-CH as a platform to share ABS information. In particular it provides access to information made available by each Party relevant to NP implementation, enhancing transparency and legal certainty and enabling monitoring of utilisation of GR along the value chain.

The ABS-CH automatically issues an IRCC when a provider country that requires PIC grants access to a GR and provides information to the ABS-CH on the permit(s) or equivalent issued at national level. Detailed information on MAT may be provided.

When a checkpoint provides information to the ABS-CH (as appropriate), the information is published in the format of a checkpoint communique. Courtesy copies of the communique record are sent automatically by the ABS-CH to the designated national authority/ies (of the country where the checkpoint is located), the national focal point (NFP) and competent national authority/ies (CNA) of the Party providing the GR and PIC, and the party/entity to whom PIC was granted (if this information is not confidential). Thus, as the GR is utilised by various users in countries that are NP Parties, the Party providing PIC is informed at particular stages – depending on the designated checkpoints.

The ABS-CH also provides a location for the sharing of other ABS information, as 'reference records' - such as model contractual clauses, codes of conduct, guidelines and best practices developed by different sectors.

2.2 EU REGULATION (EU) No 511/2014

2.2.1 Overview

The EU Regulation (EU) No 511/2014[5] establishes rules to govern compliance with ABS by users in the Member States of the EU, and a mechanism for monitoring utilisation. Further detail is set out in Commission Implementing Regulation (EU) 2015/1866[6].

As the core of the Regulation, users are obliged to exercise 'due diligence' to ascertain that the GR/ATK they utilise have been accessed (*acquired*) from NP Parties that regulate access, with PIC and MAT as necessary, and they must seek, keep and transfer IRCCs (or equivalent information) and relevant information on MAT to subsequent users. Compliance is checked at two key stages: (1) when receiving external funds for research, and (2) at final development of a product, by means of 'due diligence declarations'. The Regulation establishes a monitoring system, not a tracking system: it requires neither multiple declarations at different stages of product development nor the reporting of transfers between 'non-users' along a chain (or

[4] http://absch.cbd.int/about

[5] 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

[6] 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

network) of custody. EU-registered collections must be able to track/monitor GR/ATK, and their ability to do so will be verified regularly by Member States, but information on exchanges and sample transfers is not reported. EU-recognised best practices provide guidance developed at a sectoral level for meeting the EU obligation for due diligence.

2.2.2 Scope and definitions (Arts. 2 and 3)

The Regulation's scope is clearly defined[7] (Fig. 1): 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 is a Party to the Nagoya Protocol, with applicable access legislation, where the GR/ATK were accessed (*acquired*) on or after 12 October 2014, are not covered by a specialised international ABS instrument, *and* are non-human. The utilisation it covers is 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 (see Table 1). 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 the change of intent[8].

The Regulation uses the NP definition of utilisation of GR and CBD definitions of GR and genetic material. It does not define 'research' but the draft Guidance Document notes that basic research is included in the scope. The guidance also provides examples of activities that are not considered utilisation: 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). Access to derivatives is covered only when it is combined with access to a GR from which that derivative was or is obtained. The use of digital data obtained from gene sequencing is considered to be out of scope of the Regulation[9].

2.2.3 Obligations of users (Art. 4)

Certain user obligations are established:

- users must exercise **due diligence**[10] to ascertain that GR and ATK which they utilise have been accessed in accordance with applicable ABS legislation or regulatory requirements, and that benefits

[7] Commission Notice Guidance Document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and the Council of 16 April 2014 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. Brussels, XXX […](2016) XXX draft. Draft guidance document as provided to Commission's MS Expert Group for their meeting on 19/04/2016 as Document 2, accessed 22 May 2016.

[8] Ibid.

[9] Ibid.

[10] Due diligence is not defined. The draft Guidance Document explains 'Due diligence refers to the judgment and decisions that can reasonably be expected from a person or entity in a given situation. It is about gathering and using information in a systematic way. As such it is not intended to guarantee a certain outcome or aiming at perfection, but it calls for thoroughness and best possible efforts. Due diligence goes beyond the mere adoption of rules and measures; it also entails paying attention to their application and enforcement. Inexperience and lack of time have been held by the courts not to be adequate defences. Due diligence should be adapted to the circumstances – e.g., greater care

are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.

- GR/ATK are only to be transferred and utilised in accordance with MAT (if required by applicable ABS legislation or regulatory requirements).
- Users are to **seek, keep and transfer to subsequent users** the 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 users 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.
- Users must keep the information relevant to ABS for 20 years after the end of the period of utilisation.
- Users that obtain GR/ATK from a 'registered collection' are considered to have exercised due diligence as regards the seeking of information listed in the previous bullet points.
- Users that obtain plant genetic resources for food and agriculture from Nagoya Parties that have determined that PGRFA under its management and control and in the public domain, not contained in Annex 1 to the ITPGRFA, will also be subject to the terms of the Standard Material Transfer Agreement for the purposes set out under the ITPGRFA, are considered to have exercised due diligence.
- Obligations can be fulfilled within a minimum period after access in the case of GRs that are the causing pathogens of international public health emergencies.

2.2.4 Register of collections (Art. 5)

The Regulation establishes a register of collections. Member States can consider, upon request by a collection, the inclusion of that collection or a part of it on the register, then notify the Commission of the details, which are then included in the register. A registered collection will have demonstrated its capacity to:

- apply standardised procedures for exchanging (with other collections) and supplying (to third persons for their utilisation) samples of GR and related information in line with the CBD and the NP;
- supply only with documentation of evidence that GR were accessed (*acquired*) in accordance with ABS legislation and regulatory requirements and with MAT;
- keep records of all samples of GR supplied to third persons for utilisation;
- establish or use unique identifiers (where possible) for samples supplied
- **use appropriate tracking and monitoring tools** for exchanging samples of GR with other collections.

Registered collections will be subject to checks, taking a risk-based approach, and if there are concerns, competent authorities will carry out verification.

It is not yet obvious that many EU museums or botanic gardens will seek to be included in the register; collections that do not generally supply to third persons for commercial utilisation may not gain any particular benefit by being included – third person commercial users and the competent authorities have more to gain. Microbial collections are more likely to become registered collections, as they maintain close ties to a range of industrial sectors. However, non-registered collections still need to be able to keep

---

should be applied in riskier activities, and new knowledge or technologies may require adaptation of previous practices.'

evidence of PIC and MAT associated with specimens in order to meet due diligence declarations when necessary. The use of recognised best practices (see below) will support their abilities to do so, and to uphold their obligations and commitments to the original providers of GR/ATK.

2.2.5 Competent authorities (Art. 6 and 9)

The competent authorities are designated by each Member State to be responsible for the application of the Regulation. The competent authority receives the due diligence declarations and transmits the checkpoint communiqués to the ABS-CH, and will carry out checks to verify user compliance, using a risk-based approach and if concerns have been raised, especially by provider countries.

2.2.6 Monitoring user compliance (Art. 7)

User compliance is monitored via the transmission of **due diligence declarations** (DDDs) from users to the competent authority, who then registers a checkpoint communique on the ABS-CH (Fig. 2). There are two stages ('checkpoints' in the Regulation) of utilisation at which due diligence declarations are made:

1) At the stage of research funding, when a research project involving utilisation of GR/ATK is subject to external funding in the form of a grant. The declaration needs to be made after the first instalment of funding has been received and all the GR/ATK that are utilised in the funded project have been obtained, but no later than at the time of the final report or at the project's end. No distinction is made between public and private funding.
2) At the stage of final development of a project. This DDD is to be made only once, at the first (earliest) event occurring, of these events:
    (a) Market approval or authorisation sought for a product developed via the utilisation of GR/ATK;
    (b) Notification required prior to placing for the first time on the Union market a product developed via utilisation;
    (c) Placing on the Union market for the first time a product developed via utilisation for which no market approval/authorisation/notification is required;
    (d) The result of the utilisation is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of (a), (b) or (c);
    (e) The utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person **outside the Union**.

According to the draft Guidance Document, transfers between entities of the same company are not considered as 'transfer' in the meaning of the Implementing Regulation, so a DDD does not need to be filed, and publication of scientific papers is not considered as fulfilling the criteria of being 'sold or transferred', so a DDD is not required – but the general due diligence obligation may still apply, so the author of the paper may still need to seek, keep and transfer relevant information to subsequent users. Digital genetic information is outside the scope of the Regulation.

An online system 'DECLARE' is being developed as the entry point for 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.

2.2.7 Best practices

The EU Regulation allows for associations of users or other interested parties to have a combination of procedures, tools or mechanisms, developed and overseen by them, to be recognised as a best practice under the Regulation. The Commission may grant recognition as best practice, if it determines, based on evidence and information provided by the association that the specific combination, when effectively implemented by the user, enables the user to comply with its obligations under the Regulation. The Commission will keep an up-to-date internet-based register of recognised best practices. If there is evidence that users are not complying with the Regulation when implementing the best practice, the best practice may be examined for deficiencies.

2.3 Brazilian legislation

2.3.1 Overview

The Brazilian ABS legislation is underpinned by the Law 13.123[11] of May 20th 2015, which became effective 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[12] of May 11th 2016.

The new legislation is based on a registration and notification system (Fig. 3). The Genetic Heritage Management Council (CGen) has a central role on managing the information that is the core of the ABS compliance. Users will register using SISGen at any time while accessing (*conducting research and development on*) Brazilian genetic heritage (GH) or ATK. Users must also use SISGen to register sending samples abroad for contracted services, but this may be done before access is registered. Access must have been registered *prior* to shipping samples abroad for access, and then a separate SISGen shipment registration is required. Access must also have been registered prior to requesting intellectual property rights, disseminating results, and when economic exploitation of finished products or reproductive materials occurs; in this last case, a notification on SISGen is additionally required. International shipment for access requires an MTA in addition to registration, and economic exploitation requires a benefit-sharing agreement. When foreign institutions/organisations are involved, access in certain situations requires prior authorisation from the National Defence Council (in areas indispensable to national security) or the Maritime Authority (in Brazilian marine areas). SISGen will issue a receipt after registration (for access and shipment) and notification (for finished products/reproductive materials). 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 genetic heritage (GH) and ATK, but (like the EU measures) they do not constitute a detailed tracking system. The role and responsibilities of Brazilian collections in this context are unclear at the time of this document's preparation.

[11] Available at: http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm
[12] Available at: http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2016/Decreto/D8772.htm

2.3.2 Scope and definitions (Arts. 1-5)

The Brazilian Law 13.123 covers the goods, rights and obligations related to:

- access to the Brazilian genetic heritage (GH)[13] found *in situ* or kept in *ex situ* conditions;
- the traditional knowledge associated with genetic heritage (ATK);
- technology access and technology transfer for biodiversity conservation and utilisation;
- economic exploitation of finished product[14] or reproductive material[15] originated from GH or ATK access;
- the fair and equitable sharing of benefits arising from economic exploitation;
- the shipment[16] abroad of samples, which is intended to access the GH;
- the implementation of international treaties on GH/ATK approved and promulgated by the National Congress.

Access for research or technological development and economic exploitation shall only be realized through registration, authorization, notification, and will be submitted to surveillance, restrictions and benefit-sharing (Fig. 4).

It is important to highlight that, according to the definition in the Brazilian law (Art.2-VIII), access is research or technological development carried out on a GH sample. Sampling biological resources, for scientific or teaching purposes, performed within the national territory, continental shelf, territorial sea or exclusive economic zone may be subject to authorization by the Chico Mendes Institute for Biodiversity Conservation[17] (see IN 03 for further information).

2.3.3 Competent Authority CGen and online system SISGen (Art. 6-7)

The management, control and supervision of the activities related to GH/ATK access are competence of the Genetic Heritage Management Council (CGen), 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. The competences of CGen include:

- setting technical standards, guidelines and criteria for benefit-sharing agreements;
- monitoring activities such as sample access and shipment containing the GH/ATK;
- deliberating on the recognition of national institutions that hold *ex situ* collections.
- attesting to the regularity of access to GH and ATK by the issuance of a Certificate of Access Authority (CAR) [18];
- registering notifications of benefit-sharing agreements;
- creating and maintaining a public database[19] for information recording about GH/ATK.

---

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

[14] Finished Product: product originated from GH or ATK access whose 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 natural or legal person.

[15] Reproductive Material: plant propagating material or animal reproduction material of any genus, species or cultivation from sexual or asexual reproduction.

[16] 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 receiver.

[17] IN 03: Normative Instruction No. 03 of September 1st, 2014. ICMBio.

[18] CAR: administrative act by which the competent authority declares that access to GH or ATK complies with the requirements of this Law.

CGen will perform a verification procedure on registrations for access, sample sending and shipment, and for notifications. During the verification period, the Executive Secretary of CGen will search for irregularities in registrations or notifications; and make the counselors, members of sectorial chambers and rights protection federal agencies aware of the registrations and notifications. After this procedure, the user can request a declaration attesting that were no irregularities in the registration or notification (this is distinct from the CAR).

For managing the information regarding ABS, CGen will implement, maintain and operate the National System for Genetic Heritage and Associated Traditional Knowledge Management – SISGen, an electronic system to cover the management of registrations, prior authorisations, notifications, recognition of ex situ collections institutions that maintain samples of GH, and CARs.

2.3.5 Associated Traditional Knowledge (Arts. 8-10)

The Brazilian legislation protects the traditional knowledge associated to the GH of indigenous population, traditional community or traditional farmer against the illicit use and exploitation. Also, the legislation 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 (Fig. 5).

The ATK is considered part of the cultural patrimony and can also be deposited in databases. Any ATK is considered collective, even if only one individual of indigenous population or traditional community holds it. The access to ATK of identifiable source is conditional upon the obtaining of a Prior Informed Consent – PIC, but access to ATK of unidentifiable source does not require a PIC (Fig. 6).

2.3.6 Access, Shipment and Economic Exploitation (Arts. 11-16)

The activities of access to GH/ATK, international sending and shipment of GH samples, and economic exploitation require the registration at CGen, via SISGen, by the user. Registrations can only be made by natural or legal national persons. The international shipment of GH samples requires the signing of a MTA and economic exploitation requires the user to notify CGen and present the benefit-sharing agreement.

The following activities must be registered:

- access to GH or ATK inside the country by natural or legal person (public or private);
- access to GH or ATK by legal person headquartered abroad associated with national institution of scientific and technological research (public or private);
- access to GH or ATK realized abroad by national natural or legal person (public or private);
- international GH sample shipment[20] for the purpose of access;
- GH sample sending[21] by national legal person (public or private) to provide services abroad as part of research or technological development.

---

[19] Information in this database are public, except those that may prejudice the scientific research or technological development activities or third parties' commercial activities, although the information may be available by user's authorization (Art. 12, § 3).

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

[21] 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 performs the access in Brazil.

The access registration should be done prior to shipment, to the request of any intellectual property right, to the commercialization of the intermediate product, to the dissemination of results (final or partial) in scientific or communication means, or to the notification of finished product or reproductive material developed as a result of access. Access does not have to be registered prior to sending samples for services provided abroad.

Some activities may be carried out only with a prior authorization from national authorities as follows:

- access to GH or ATK in indispensable to national security area - The National Defence Council decides and gives the authorization;
- access to GH or ATK within Brazilian's territorial waters, continental shelf and exclusive economic zone – the Maritime Authority decides and gives the authorization.

This prior authorization 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 person headquartered abroad;
- a Brazilian natural person associated, funded or contracted by a legal person headquartered abroad.

2.3.7 Benefit-Sharing (Art. 17-34)

According to the Brazilian ABS Legislation, the benefits arising from economic exploitation of finished products or reproductive material originating from access to GH of species found in *in situ* conditions or access to ATK must be shared in a fair and equitable way. A Benefit-Sharing Agreement must be settled between the one who economically exploits the finished product or reproductive material originated from access of GH/ATK and the ATK provider (or the Union, in the case of unidentifiable source ATK or only GH access).

The National Fund for Benefit-Sharing (FNRB) has a financial nature and it is linked to the Ministry of Environment with the aim of enhancing the GH/ATK and promoting their use in a sustainable manner. The revenues of FNRB are: amounts assigned in the annual budget law; donations; amounts collected with the payment of fines from the violations of Law 13.123; financial resources of external origin from contracts, agreements or arrangements especially reserved for the purposes of the FNRB; contributions made by GH or ATK users; values from the sharing of benefits; and other revenues that may be addressed to it.

Monetary funds deposited in FNRB arising from access to ATK are used exclusively for the benefit of ATK holders. Funds deposited in FNRB arising from access to GH obtained from recognised *ex situ* collections is partially allocated to these collections.

2.3.8 Collections

There are no obligations for collections regarding their role in this context. At the moment of writing, it is not defined how CGen will accredit Brazilian collections; the law only provides that they must conduct an online registration for recognition by CGen. This may be a gap for tracking GH if no assessment approach is put in place in order to assure the keeping of evidence, such as PIC, MTAs and permits.

2.4 Bridges and gaps: how do EU and Brazilian measures work together?

Comparing the Brazilian ABS law and the EU ABS regulation, it is clear that both are systems for monitoring utilisation (as required under the NP): the EU due diligence measures will enable certain monitoring of utilisation of Brazilian genetic resources by EU users (at the stages of research funding and final development of a product), and the Brazilian system will monitor utilisation in Brazil and abroad at the key stages of access (*research and development*) and export. Neither provides (or imposes) a detailed tracking mechanism. The Brazilian registration system provides trackable numbers that facilitate both tracking and monitoring and the EU due diligence obligation provides support for tracking, as users must seek, keep and transfer certain information to subsequent users.

It can be especially challenging to understand how the frameworks do and do not work together when they (and the Protocol) use the same terms for different concepts, or different terms for very similar concepts. The key terms are compared in Table 1.

2.4.1 Nagoya Protocol ratification

The EU regulation covers the utilisation of material that is accessed (*acquired*) from its country of origin after 12 Oct. 2014, the date of entry into force of the regulation and of the Nagoya Protocol (and after the entry into force of ABS legislation in the provider country). **In the case of Brazil, a non-Party at the time of this document's preparation, the EU regulation will only apply to Brazilian material accessed (*acquired*) after Brazil becomes a Party**. The regulation does not require due diligence measures and declarations for the post-Nagoya utilisation of material acquired pre-Nagoya (or before the date upon which Brazil becomes Party to the NP), so Brazil will not be notified via checkpoint and ABS-CH of such utilisation. Reporting on obligations stemming from the Provisional Measure[22] will rely on the terms of MTAs and other contractual agreements. Another temporal difference arises from the Regulation's requirement for EU users to keep the ABS information for [only] 20 years after the end of the utilisation.

2.4.2 Externally vs. internally-funded research

Brazil will receive information about utilisation in the EU when research is initiated if it is externally funded, but not if internally funded. If no product is placed on the EU market, and the results of utilisation are not sold or transferred to others inside the EU (after the utilisation has ended) or outside the EU, no information about utilisation will flow to Brazil via the EU checkpoint and ABS-CH. Such information transfer will rely upon compliance with terms of MTAs or other agreements that communicate the CGen requirements.

2.4.3 Users vs. intermediaries, EU users vs. other foreign users

Brazil will not receive information under the EU regulation system if Brazilian material is acquired by a person, collection or company in the EU but then supplied to a non-European entity for utilisation, unless that entity is in a Party to the NP that mandates reporting under its legislation. Non-users are not subject to the due diligence obligation; transfers of GR between intermediaries along a supply chain are not monitored. If utilisation occurs but a product is not developed or the result of the utilisation is not transferred, Brazil will not be informed (except as established under terms of MTAs or other agreements/permits). Neither system requires reporting at every step of transfer or utilisation; the key stages are the initial research (if externally-funded research, in the EU), international transport (Brazil) and final products (both).

[22] The Provisional Measure (Medida Provisora, MP), was in force from 23 August 2001 until 20 May 2015.

2.4.4 Access vs. access

The different Brazilian and European interpretations of 'access' may provide some opportunities for confusion (Table 1), although perhaps less so if the Brazilian term 'access' covers the same research and development activities as the EU term 'utilisation', e.g. regarding molecular systematics. The EU regulation requires users to exercise due diligence to ascertain that the GR they utilise have been accessed (*acquired*), in accordance with applicable ABS legislation. Where specimens are initially accessed (*acquired*) for non-molecular research, they will need to be covered by the appropriate Brazilian permits for acquisition, transport and, if applicable, export. If the same, or other, researchers later wish to utilise these specimens for molecular taxonomic research, they will need to register such access (*research and development*) on the Brazilian system. It is not clear whether the initial non-access permits are required when making a registration on SISGen. Any such requirements need to be set out very clearly for scientific users, because they may occur frequently. In particular, the requirements for legal export/shipping/import need to be very clear so that unnecessary quarantine, confiscation or destruction does not occur.

2.4.5 Genetic heritage vs. genetic resources

Likewise, some confusion may be caused by the usage of 'genetic heritage' vs. 'genetic resources'. The Brazilian genetic heritage definition includes 'information', which could be taken to include genetic sequences, and 'substances derived from the metabolism of these living beings', akin to the Nagoya definition of derivatives. The EU regulation guidance applies strictly to genetic resources; access to derivatives is only covered when the derivatives are contained within the genetic resource. Again, EU users will need to work via the terms established under Brazilian arrangements.

The EU draft scope guidance clarifies that digital data obtained from gene sequencing, which is frequently stored in publicly available databases, is currently outside the scope of the EU regulation; however the use or publication of such data may be covered by mutually agreed terms in an access agreement. Brazilian Decree 8772 (Art. 107-VI) provides that the comparison and extraction of genetic information from national and international databases is not considered access when it is not part of research or technological development. It seems likely that uploading sequence information *to* publicly available databases is considered 'access' in Brazil, but it is not clear how the EU and Brazilian measures apply to the routine comparison of genetic sequences for identification and phylogenetic analyses.

2.4.6 Non-commercial vs. commercial utilisation

Both legislative systems are clearly targeted towards the reporting of commercial outcomes, although the EU regulation thus far (based on draft guidance) will also potentially include upstream basic research, such as DNA sequencing for taxonomic purposes, as does Brazil's law (molecular taxonomic research was previously excluded).

Scientific research results are typically transmitted to the public domain via publications and public databases, neither of which would trigger EU due diligence declaration at stage of final development. Brazil will thus not receive information about *results* of non-commercial utilisation via the NP system of checkpoints and ABS-CH (only that certain externally-funded research will be or has very recently been conducted by a certain user); the sharing of results from such utilisation will be addressed via the terms of acquisition from Brazil, via MTAs and collecting permits.

3. COLLECTING, TRANSPORTING AND SHIPPING GENETIC RESOURCES FROM BRAZIL

First, it is important to note that the following text concerns the export of genetic heritage (GH) from Brazil to abroad and does not apply for every kind of biological material shipment. Secondly, some rules on the transfer of GH samples might be applicable for both sides – the sender and the receiver. The country that is shipping GH samples must comply with its own rules but should be aware of the possibility of mandatory compliance with the receiver's rules for this kind of shipment from outside the country. To do so, the exporter must obtain from the importer the mandatory list of documents which should be provided for the entry of the goods in the destination country.

Shipping has always been a delicate theme when talking about GH transfers. Usually the infractions involving improper shipment abroad of Brazilian biodiversity components are probably not committed wilfully. Most of the users believe that the procedures are bureaucratic and do not have knowledge of legal norms applied (Siqueira, 2014)[23]. In fact, it is very time-consuming (and can be very expensive too) to comply fully with all the requirements and procedures from different agencies that may be involved in this process (Fig. 7).

3.1 Collecting and transporting samples within Brazil

In Brazil, independently of the purpose or route of the GH shipment, the procedures may involve the evidence of its origin from in situ conditions. The acquisition of biological material in the country is regulated by the Chico Mendes Institute (ICMBio), under the Ministry of Environment, through the Normative Instruction No. 03 of September 1st, 2014 (IN 03). IN 03/2014 covers activities for scientific or teaching purposes performed within the national territory, continental shelf, territorial sea and exclusive economic zone. Those activities are:

I. collection of biological material;
II. capture or tagging of wild animals *in situ*;
III. temporary maintenance of wildlife specimens in captivity;
IV. transport of biological material;
V. conducting research in Federal Conservation Units or natural underground cavity (caves).

The scope of IN 03 does not include the collection and transport of biological material from:

- domesticated or cultivated species, except when related to research in federal conservation units;
- exotic wildlife in *ex situ* conditions.

All the applications must be done through the SISBio information system[24], which was developed and is maintained by the Ministry of Environment. The permit to collect and transport is granted after an assessment of the information provided with the application via SISBio.

3.1.1. Permanent licence

It is possible to apply for a permanent licence for collecting and transporting biological material. In this case the applicant must be a researcher with a doctoral degree or equivalent, recognized in Brazil, and a current

[23] Siqueira, I. Normas ambientais aplicadas ao envio de material biológico ao exterior com finalidades científicas. 2014. Available at: http://www.ib.usp.br/pesquisa/images/arquivos/Envio_de_material_biologico_ao_exterior.pdf.
[24] http://www.icmbio.gov.br/sisbio/

employment relationship with the scientific institution involved in the project. The permanent licence will be valid for the duration of the employment of the researcher in the scientific institution at which he or she was affiliated at the time of application. The authorization may be granted to retired researchers, when formally appointed by scientific institution. The permanent licence is personal and not transferable.

The holder of the permit or permanent licence and the members of that team must identify the locality and the collection methods and tools for capture appropriate for the taxonomic group of interest, avoiding death or damage of other groups. The efforts to collect or capture must not compromise the *in situ* population viability of the taxonomic group. The unexpected collection of biological material or substrate not covered by the authorization or permanent licence must be noted at the time of collection. The transport of biological material or substrate must be accompanied by the authorization or permanent licence, annotated for any unexpected collections. The collection must be communicated in a report to ICMBio and the collected material must be destined for the scientific institution.

3.1.2 Destination of the Collected Material

The collected biological material should be deposited in a scientific biological collection[25]. The deposit of microbiological material can be made in the national service collection or depositary centre; when necessary, the deposit also can be made in a reference collection abroad by the institution with which the researcher is affiliated.

3.1.3 Transportation, Receiving and Sending of Biological Material

The permanent licence and collection authorization cover the transport of biological material for scientific purpose that is not already registered in a scientific collection. The permit or permanent licence is for transport between the locality where the field collection was made and the receiving institutions specified in the licence/authorization application. If the receiving institution is not included in the permanent licence or collection authorization, its inclusion must be requested via SISBio. The transportation outside the country of the biological material covered by the permit must comply with the specific legislation for international transit (see below).

3.2 International Transit and Surveillance

3.2.1 Agricultural Surveillance

To prevent the spread of diseases and pests, Brazilian legislation prohibits the import into and export from the country of plant products without authorisation from the Ministry of Agriculture (MAPA). Supervision and inspection is covered by the International Agricultural Surveillance System – VIGIAGRO, which is the organ of the Agricultural Defense Secretariat responsible for performing the surveillance activities. Currently, the VIGIAGRO system consists of Services Agencies (SVA) and Agricultural Surveillance Units (UVAGROs), located in ports, airports, border crossings and special customs. For managing the information about international transit of agricultural goods VIGIAGRO uses the Management Information System for the International Transit of Products and Agricultural Supplies– SISVIG. This system is intended to manage and

[25] Scientific Biological Collection: Brazilian collection of biological material properly handled, maintained and documented in accordance with standards and norms that ensure safety, accessibility, quality, longevity, integrity and interoperability of data, belonging to scientific institution with the aim of support scientific and technological research and *ex situ* conservation (ICMBio IN 03, Art. 6).

control the receiving, shipping and inspection of imported and exported goods through ports, airports and borders, with a single register of authorised establishments, representatives, and import/export requirements. The operational procedures for international agricultural surveillance are established by the Normative Instruction 36 of November 10th 2006. The procedures and documents required for the application of the authorisation are available at MAPA's International Transit Manual[26].

According to MAPA, customs transit is characterized by the transit of goods between bonded enclosures under customs control of the Brazilian Federal Revenue. A VIGIAGRO unit issues a customs clearance of export and the goods are inspected according to the export procedures described in specific chapters of the international transit manual. The required and issued documents may vary depending on the case (also described in specific chapters of the manual); but some of them, required for any kind of goods, include:

I. Documents required before transit:
- Inspection of Agricultural Products Application (FORM V);
- Phytosanitary, Sanitary or Animal Health Certification, depending on the case;
- other documents required as chapter or section related to the product in customs transit;
- copy of the pro forma invoice (issued by the sending institution);
- Export Registration (RE);
- loading plan, when applicable;
- import permit from the destination country, when applicable;
- CITES permits issued by IBAMA, when applicable;
- ICMBio Permit (to prove legal Brazilian origin of material)
- National Register of Seeds and Seedlings (REANSEM) and National Register of Cultivars (RNC), when applicable;

II. Documents required in the bonded warehouse for dispatch of export goods (early customs transit):
- application for inspection of agricultural products (FORM V);
- other documentation provided in the specific section related to the goods;
- document from Brazilian Federal Revenue testifying the customs transit for export;

III. Documents required in the bonded area of airport, port or border post:
- Inspection of Agricultural Products Application (FORM V);
- International Health Certificate, when applicable;
- Customs Transit Permit (ADTA) issued by VIGIAGRO unit from the bonded area of the goods' origin;
- copy of the Cargo Manifest.

IV. Documents issued:
- Inspection Term (FORM VII), in which the conclusion/observation field indicates whether the customs clearance will be granted or denied, or if requirements should be met;
- Phytosanitary, Sanitary or Animal Health International Certificate, for cases of tran-shipment or loading in special customs;
- ADTA (XXI FORM) in triplicate;
- Occurrence Term (FORM XII), where applicable;
- other documents required by specific chapters or sections related to the product in customs transit.

[26] http://www.agricultura.gov.br/portal/page/portal/Internet-MAPA/pagina-inicial/servicos-e-sistemas/servicos/Transito-internacional

Before granting phytosanitary authorisation, MAPA may also require approval from the National Plant Protection Organization (NPPO) of the country of destination regarding Brazil's phytosanitary requirements.

3.2.2 Health Surveillance

Health surveillance in Brazil is the responsibility of the National Agency for Health Surveillance (ANVISA). ANVISA ensures the health control of ports, airports and borders, as well as protecting the health of the traveller, means of transport and services subject to health surveillance. This agency monitors compliance with health standards and the adoption of preventive measures and control outbreaks, epidemics and public health threats, and controls the import, export and circulation of raw materials and goods subject to health surveillance, the International Health Regulations and other acts and treaties signed by Brazil. ANVISA becomes involved in the shipment and international transit of GH when the sample is of health concern and contains human derived material. When this is the case, the user must submit the Monitoring Application and Exported Cargo Sanitary Clearance[27], and the Terms of Responsibility for Scientific Research of Sanitary Interest[20]. Other documents, and permits might be necessary according to the material or product involved. Further information can be accessed from the ANVISA website[28].

3.3 Convention on International Trade in Endangered Species of Wild Fauna and Flora - CITES

CITES, to which Brazil and all EU Member States are Party, provides the international legal framework for the regulation of international trade of species of fauna and flora, by certifying sustainable trade and preventing trade in species facing extinction through over-exploitation, via the issue and control of import and export permits for species listed in its three Appendices.

Countries may take stricter measures under CITES, as the European Union and its Member States have done: Brazilian users wishing to import into or export from Europe must check the EU's four Annexes to see what permits apply[29].

Based on the procedures proposed by the Convention, the Brazilian Government through the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) has incorporated procedures for evaluation and issuance of export permits. IBAMA is Brazil's CITES Management Authority, CITES Scientific Authority and also CITES Enforcement Agency.

IBAMA's CITES Service[30] is an online system through which exporters request CITES permits. The service involves the request by a user for the permits, analysis of the application and issue of permits by IBAMA. It is important to note that to export the products and sub-products from fauna together with the flora ones, the user must register at least one activity related to wildlife and at least one related to flora in the system,

[27] Available online at: http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Inicio/Portos+Aeroportos+e+Fronteiras/Assunto+de+Interesse/Exportacao/Listagem+de+Nomenclatura+Comum+Mercosul+NCM

[28] http://portal.anvisa.gov.br/registros-e-autorizacoes

[29] http://ec.europa.eu/environment/cites/index_en.htm; EC and TRAFFIC. 2015. Reference Guide to the European Union Wildlife Trade Regulations. European Commission, Brussels, Belgium, and TRAFFIC. http://ec.europa.eu/environment/cites/pdf/referenceguide_en.pdf

[30] https://servicos.ibama.gov.br/index.php/autorizacoes-e-licencas/importacaoexportacao-de-flora-e-fauna-cites-e-nao-cites/135-requerimento-cites

otherwise the CITES application that contains both types of products and sub-products will be rejected at the time of analysis. If the user intends to export a GH sample from the fauna or flora listed on CITES, the registration as exporter[31] should be done prior to the permit request.

3.4 Exporting of biodiversity specimens for research purposes

IBAMA also authorizes the export of specimens, products and sub-products of native biodiversity for the purpose of research. To apply for the permit, the user or institution that will conduct scientific research must be registered in the Federal Technical Registration of Potentially Polluting Activities and Use of Environmental Resources. This is a mandatory registration of individuals and legal entities that perform activities subject to environmental control. Such activities subject to registration are listed in a table[32] and activities involving GH are classified in four categories (20-5; 20-37; 20-41 and 20-61).

3.5 CTNBio

The National Technical Committee on Biosecurity (CTNBio) is a multidisciplinary collegiate body under the Ministry of Science, Technology and Innovation. Its purpose is to provide technical advisory support to the Federal Government in the formulation, updating and implementation of the National Biosafety Policy relating to genetically modified organisms (GMOs), and the establishment of technical safety standards and technical advice relating to the protection of the human health, living organisms and environment, for activities involving the construction, testing, cultivation, handling, transport, marketing, consumption, storage, release and disposal of GMOs and derivatives. For the transport of GMOs, the user should apply to the Biosecurity Internal Committee (CIBio) of its institution for an 'opinion request' (pedido de paracer). CIBio forwards the application to CTNBio, which decides and alerts CIBio and the surveillance/registration bodies.

3.6 CNPq

The National Council for Scientific and Technological Development (CNPq) issues authorisations for Scientific Expeditions. The authorisation covers research and collection of scientific material by foreigners in Brazil, as well as the shipment of this material abroad. For this purpose, scientific material is classified as any 'data, material itself, biological and mineral specimens, with the purpose of scientific studies, research and dissemination'. The activities are characterized as cooperation activities involving exchanges of knowledge between Brazilian and foreign scientists through their institutions, through scientific research and technological development projects. This kind of activity depends upon authorisation from the Brazilian Government, granted through an Edict issued by the Ministry of Science, Technology, Innovation and Communication (MCTIC). To obtain this authorisation, the Brazilian institution responsible for the project must present to CNPq the application, according to the rules established at the federal laws, including the Decree nº 98.830/1990 and the MCTIC Regulatory Act nº 55/1990. The procedure for requesting the authorisation is available on the website[33] and sets out the necessary steps to be followed by the Brazilian counterpart. The foreign counterpart is responsible for the funding of the activities. It is important to note that the CNPq grants and scholarships cannot be used to finance Scientific Expeditions. It is assumed that the scientific Brazilian counterpart can contribute the necessary support and the institutional infrastructure, including equipment and staff, as pre-established by the collaborative international partnership.

[31] https://servicos.ibama.gov.br/index.php/autorizacoes-e-licencas/importacaoexportacao-de-flora-e-fauna-cites-e-nao-cites/259-requerimento-cites-cadastro-de-importador--exportador
[32] https://servicos.ibama.gov.br/phocadownload/manual/tabela_de_atividades_do_ctf_app_set-2015.pdf
[33] http://cnpq.br/como-solicitar/

3.7 Other National Agencies

Other national agencies such as National Agency of Ground Transportation (ANTT) and National Agency of Civil Aviation (ANAC) do not provide authorizations but they do have requirements for the shipment and transport of biological material of Risk Group 2 or above (according to WHO classification), concerning labelling and the safety sheets that accompany goods. All the requirements regarding the packaging of dangerous goods follow the International Rules from Universal Post Union and International Air Transport Association (IATA). Other requirements are applicable for transportation companies and not for GH users.

3.8 SISCOMEX Portal

SISCOMEX Portal[34] is an e-government initiative focused on increasing transparency and efficiency in the processes and controls of exports and imports. It is geared primarily to foreign trade operators - exporters, importers, transporters, keepers, customs brokers, port terminals, etc. Its objective is to simplify access to government services and systems and relevant legislation for foreign trade operations. All components of this Integrated Foreign Trade System and other government systems for obtaining permits, certifications and licences to export or import are present in the SISCOMEX Portal. Through it, the foreign trade operators also have easier access to the rules governing imports and Brazilian exports, organized by the responsible body for editing or management of the rule in question. SISCOMEX has been widely used by public institutions in order to address issues such as export of biological resources, including GH samples.

3.8 Brazil Post

One of the most common ways of send objects is by the Brazil Post, and it is possible to export GH samples (not classified as dangerous goods) by this means. The Brazil Post requires that the following documents[35] accompany the order: commercial invoice, pro-forma invoice, postal form or air waybill (internationally recognized as AWB), certificate of origin for the goods, and other documents and information depending on the type of export chosen by the costumer.

4. SECTORAL TRACKING SYSTEM WORKFLOWS AND BEST PRACTICES

How do different sectors currently link material and ABS information? This workshop gathers participants from across many different sectors that handle genetic resources in different forms and for different purposes; this section of the paper describes general considerations and then provides examples of tracking systems drawn from different sectors that utilise GR.

[34] http://portal.siscomex.gov.br/
[35] http://www.correios.com.br/para-voce/envio/exportacoes/documentos-para-exportacao

4.1 General considerations for a tracking system

4.1.1 Viable vs. non-viable GRs

The type of tracking system is in part determined by the nature of the genetic resources. In an extensive 2009 review of identification, tracking and monitoring of genetic resources, Garrity et al.[36] compared:

- Viable GRs – these can be re-propagated, such as microbial cultures, crop germplasm, living plant and animal specimens, cryopreserved gametes; to some extent, purified nucleic acids can now be considered as viable GRs, as they can be replicated
- Non-viable GRs – such as whole or parts of animals and plants that cannot be propagated by users, though they may increasingly be used for DNA extraction
- Derivatives of GRs – the full complement of products of gene expression that could trigger a detection assay, including proteins, lipids, carbohydrates, organic acids or complex primary or secondary metabolites that might be discovered.

Clearly, the nature of what could be considered to be 'viable' is changing over time, as technology is increasingly allowing the extraction of replicable genetic sequences from older preserved material. However certain genetic resources are explicitly held for their viability purposes – e.g. agricultural and horticultural germplasm, and the living collections of botanic gardens and seed stored in seed banks for conservation. Museum and herbarium collections, though many might now be capable of providing DNA, which can be replicated, are not themselves viable for re-propagation.

4.1.2 Use of the tracked material

The type of tracking or monitoring system is obviously related to the nature of genetic resource use e.g. whether for non-commercial taxonomy, conservation or for the development of a product for the market. Different uses have different potential risks associated with mislabelling (legal or otherwise) and so are likely to determine the scale of the financial and human resources devoted to tracking.

Agricultural and horticultural germplasm is often kept for breeding purposes, and breeders must be able to keep track of lineages, while botanic garden and seed bank collections are more likely to be kept for species preservation – for which taxonomic identity and geographic provenance are important, but precise lineage information is less crucial, though genetic variability is of increasing concern.

Particularly for *ex situ* collections, the size and age of an institution will also affect the level of tracking possible. Larger, older institutions that use material for non-commercial purposes are likely to have a much smaller proportion of their collections digitised.

4.1.3 Identifiers for ABS

Many different identifiers are used to identify objects of interest to ABS: the access permission, researchers, localities, suppliers, specimens, taxonomic names, DNA sequences, publications, compounds, organisations. Various identifiers can be used to help track the country of origin of a GR, or the GR used for a piece of published research, or the voucher specimen from which a DNA sequence was derived. Collections' accession numbers can provide a valuable link between an acquisition event, the legal documentation and

[36] Garrity G, Thompson L, Ussery D, Paskin N, Baker D, Desmeth P, Schindel D, Ong P. 2009. Studies on Monitoring and Tracking Genetic Resources. United Nations Convention on Biological Diversity; 2009. Report No. UNEP/CBD/WG-ABS/7/INF/2, p. 21-3

other metadata, and one or more physical specimens. Some collections use physical barcodes to keep track of specimens and samples.

Persistent identifiers are unique identification codes that are effectively permanently assigned to an object. Although a Globally Unique Identifier (GUID) is in theory the same thing as a persistent identifier, GUIDs emphasise global uniqueness rather than persistence[37]. As information related to material is uploaded to public (or other) databases, such as the Global Biodiversity Information Facility (GBIF), computer-readable, actionable persistent unique identifiers are increasingly vital components of any system for the organisation and cross-linkage of highly diverse information[38].

Use of persistent identifiers would support a truly global ABS tracking system – but there is currently no uniformity between or within sectors as to what identifiers are used for the GR and associated information that they handle and utilise. The identifiers applied to GR are not necessarily globally unique or persistent. Companies may use sophisticated laboratory information management systems (LIMS) for the transfer of physical samples and data from one individual to another but such internal systems only need to use locally unique identifiers (Garrity et al. 2009).

The IRCC identifier is designed to be globally unique and persistent, and much more trackable than conventional paper certificates. However, if several permits were required for legal acquisition (e.g. collecting and export permits as well as an access permit), a tracking system also needs to be able to keep those documents and their terms associated with the identifiers for the GR and its samples and derivatives.

The IRCC or other permit granted for access is an identifier for the ABS information, not the GR, the users or the results of utilisation. An IRCC will quite often cover multiple GR in a batch, with individual GR not identified to species level for some time. As the batch is gradually separated and identified, new identifiers may need to be assigned to individual GR, to samples as they are taken, to derivatives that are extracted or isolated. If samples or derivatives are combined in a product, a tracking system needs to be able to handle several identifiers for one object.

4.2 Sectoral examples of tracking and monitoring systems

A generalised picture of how GR travel from *in situ* conditions in provider countries through *ex situ* conditions (in a range of different types of collections) and then into utilisation by a range of sectors, and possibly, via derivatives and products, eventually to market, is presented in Fig. 8. The figure also shows the points at which the IRCC and MTAs (ideally) apply, to ensure that terms travel with GR. Sectors differ in how they utilise GR and the forms of GR that are involved, and consequently they have developed quite different tracking and monitoring systems. There follows an indicative range of systems, as well as, where available, the existing best practices under which these users are working.

[37] GBIF (2011). A Beginner's Guide to Persistent Identifiers, version 1.0. Released on 9 February 2011. Authors Kevin Richards, Richard White, Nicola Nicolson, Richard Pyle, Copenhagen: Global Biodiversity Information Facility, 33 pp, accessible online at http://links.gbif.org/persistent_identifiers_guide_en_v1.pdf.

[38] Ibid.; note that our paper does not discuss further details, e.g. what is needed to make a persistent identifier 'actionable.'

4.2.1 Microbial collections

4.2.1.1 Microbial collections utilisation of GRs

Microbial resources are used in different sectors, but are essential tools for the environment, industry, health and agriculture sectors. Culture collections have been preserving organisms and supplying them for research and development for over a century. The term 'culture collection' actually does not reflect a common standard, however, since tasks, holdings, size, funding system, affiliation, mandate, and other parameters differ widely. Though the basic principles of operation are the same, namely, accessioning, maintenance, and provision of microorganisms, collections may significantly differ from each other, and hardly any two collections operate under the same system (Smith 2013)[39]. The common goals of collections and their same basic operations for collection functioning triggered the need for better cooperation and networks were created in Europe and Brazil. Even so, issues related to accessing and exchanging material are still complex in terms of legal compliance.

4.2.1.2 Post-Nagoya best practice tools: OECD, MIRRI, TRUST

The Organisation for Economic Co-operation and Development (OECD) established the concept of Biological Resource Centres (BRC)[40] and stressed their importance in the developing bioeconomy. The general concept of a BRC presented at that time includes service providers and repositories of the living cells, genomes of organisms, and information relating to heredity and the functions of biological systems. By implementing the OECD Best Practice Guidelines for BRC[41], many service collections evolve into professional *ex situ* repositories of biodiversity and distribution nodes for known, validated and precisely identified microbial resources and associated information to legitimate end-users. These microbial biological resource centres (mBRC) may be the preferred mechanism for the appropriate exploitation of microbial resources by offering the guarantee of accessibility and of transparency of supply, taking into account all relevant regulations and stakeholders' rights, as required by the Convention on Biological Diversity (CBD)[42].

OECD best practices focus on the following criteria:

- Achieving the primary objective to maintain strains in a viable state without morphological, physiological, or genetic change;
- Implementing best practice in the provision of services by ensuring:
  - Authentication of biological materials;
  - Validity of data;
  - Continued availability and reproducibility of materials;
  - Safe and legitimate shipping;
  - Legitimate acquisition of biological material;
  - Compliance with biosafety and biosecurity guidance;
  - Protection of intellectual property rights, particularly for patents.

[39] Smith D, Fritze D, Stackebrandt E. 2013. Public Service Collections and Biological Resource Centers of Microorganisms. In: Rosenberg E, DeLong EF, Lory S, Stackebrandt E & Thompson F (eds) The Prokaryotes: Prokaryotic Biology and Symbiotic Associations. Springer, Berlin & Heidelberg, pp. 267-304. Available at: http://link.springer.com/referenceworkentry/10.1007%2F978-3-642-30194-0_14.

[40] BRCs contain collections of culturable organisms (i.e. of the four domains of life: micro-organisms, plant, animal, and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms cells and tissues, as well as data bases containing molecular, physiological and structural information relevant to these collections and related bioinformatics (OECD 2007).

[41] http://www.oecd.org/sti/biotech/oecdbestpracticeguidelinesforbiologicalresourcecentres.htm

[42] Janssens D, Arahal D, Bizet C, Garay E. 2010. The role of public biological resource centers in providing a basic infrastructure for microbial research. Research in Microbiology 161(6): 422–429.

- Applying long-term methods of preservation essential to ensure availability of biological materials for the long-term;
- Selection of most suitable methods;
- Viability, purity, and stability.

The Microbial Resource Research Infrastructure (MIRRI) is a Pan-European distributed research infrastructure that provides facilitated access to high quality microorganisms for research, development and application and connects public microbial domain Biological Resource Centers (mBRCs) with researchers, policy makers and other stakeholders to deliver biological material and services more effectively and efficiently to meet the needs of innovation in biotechnology. The infrastructure has developed a legal operational framework by which it can assure compliance of its partner mBRCs with the Nagoya Protocol on Access to Genetic Resources and the fair and equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity.

MIRRI has developed a policy statement on how MIRRI partner mBRCs commit themselves to contributing to reaching the main objectives of the CBD while operating in compliance with all applicable national and international laws on ABS and regulatory requirements. Also, MIRRI has developed a Best Practice Manual on ABS[43] in order to provide guidance for the mBRCs in implementing their ABS institutional policies with regard to genetic resources and associated traditional knowledge, and working procedures for the acquisition of material, including accession, i.e., formal acceptance of new material in the public collections of the mBRCs, for transfer of material including supply to third parties and the delivery of other services. It also aims to increase transparency on how the mBRCs themselves conduct research on their holdings and lawfully utilize the GR and ATK.

TRUST - TRansparent User-friendly System of Transfer, for Science & Technology - is an initiative from World Federation of Culture Collections (WFCC) and the Belgian Coordinated Collections of Micro-organisms (BCCM)[44]. It aims at managing the obligations of the CBD and the NP on the scientific, technical and administrative activities of culture collections and, more generally, at incorporating the legal obligations and the ethical standards into the daily life of microbiologists.

TRUST is a modular system that comprises four elements (Fig. 9):

1. Updated MOSAICC[45] features with administrative workflows adapted to the structure of the NP and improved in light of past experience;
2. Refined Material Accession Agreement (MAA) and MTA models with standardized definitions;
3. An integrated data management and processing system, the Global Catalogue of Microorganisms (GCM)[46] able to provide for any information related to microbial material;

[43] http://www.mirri.org/fileadmin/mirri/media/Dokumente/generalDocs/MIRRI_ABS_Manual_web.pdf. The content has been guided by the draft EU Guidance Document; further sectoral guidance will be developed in the near future (D. Smith, pers.comm. 24/05/2016)

[44] http://bccm.belspo.be/projects/trust

[45] MOSAICC is a tool to support the coherent implementation of the CBD, the TRIPS agreement and the Budapest Treaty at the microbial level, in accordance with relevant rules of international and national laws. It is a voluntary Code of Conduct. Its purpose is twofold: to facilitate access to mGR and to help partners to make appropriate agreements when transferring them.

4. Cooperative structures within the WFCC where culture collections, *inter alia*, conduct and facilitate research in genomics and functional genomics, and conduct their efforts in networks in conformity with NP provisions on technology transfer, collaboration and cooperation.

TRUST enables the monitoring and tracking of transfers of mGR so that individuals and groups that are entitled to benefits for their contribution to the study, conservation and sustainable use can be identified. The process has three stages:

1. The *in situ* origin of a sample of microbial genetic resources (mGR) is identified and recorded via initial Prior Informed Consent (PIC) procedure of notification and/or authorisation for sampling. An IRCC is issued as proof (where providers are NP Parties and regulate their GR). GUIDs are assigned to samples (each of which may contain one or more mGR).
2. When the mGR is deposited in an *ex situ* collection as a strain, it receives another GUID . This code is kept throughout transfers and linked to the sample GUID. The deposit of mGR into a collection is made under a Material Accession Agreement (MAA) that records basic data such as place and date of sampling, etc. in a standardized form, and specifies the role, rights and duties of depositor and collection. These data are compiled in catalogues and are usually publicly accessible.
3. Transfers of mGR are recorded by the collection and occur under MTAs in which terms are defined and accepted by both recipient and provider. MTA is a generic term that covers short shipment documents, simple standard delivery notices, standard invoices containing minimal standard requirements, or more detailed, specific, tailor-made contracts. According to the use and intended distribution of the mGR, the mutually agreed terms of the contracts can be short or very detailed.

Combining the World Data Centre for Microorganisms (WDCM) registration system of culture collections and the use of electronic GUIDs, TRUST sets up a robust system to track the movements of microbiological resources and related information, and trace their origins, thus facilitating ABS compliance. TRUST also recommends the OECD Best Practices for BRCs and the WFCC Guidelines[47] for the Establishment and operation of culture collections. These documents provide guidance and propose best practices for depositories of biological material. They contain lists of rules and regulations as well as useful references.

The Brazilian Conformity Assessment System for Biological Resource Centres[48] is a governmental effort to improve the quality management in service collections and a step forward in the consolidation of the Brazilian BRC Network (CRB-Br). The advances are a consequence of decades of initiatives, involving Brazilian institutions such as Ministry of Science, Technology and Innovation, accreditation body (Inmetro), National Institute of Intellectual Property, public collections from national R&D institutions (Fiocruz, Embrapa, Unicamp), a cell bank (BCRJ), and other partners, towards the definition of a mechanism for third party assessment and procedures for accreditation, structured to highlight the demonstration of a BRC's technical

[46] The GCM is an initiative of WDCM to link all possible data to the culture collections' catalogues and make them accessible at once. Once an organism is deposited in a WFCC member collection and is assigned a number it can be traced through all publications that mention it, including patent files. Available at: http://gcm.wfcc.info/overview/

[47] World Federation for Culture Collections Guidelines for the Establishment and Operation of Collections of Cultures of Microorganisms. 3rd Edition, February 2010. http://www.wfcc.info/guidelines/

[48] Holanda P, Cavalcanti E, Borges R, Souza W. 2012. Conformity Assessment for Biological Resource Centres (BRC): The Brazilian Approach. World Federation for Culture Collections. Newsletter 52

competence in developing its activities. The plan to consolidate the CRB-Br takes into consideration all the relevant aspects of metrology, standardization, conformity assessment, and legal compliance.

The implementation of this system enables the availability of mGRs and associated information of proven quality, representing a step towards implementation of the ABS legislation and GH monitoring systems, since the key requirement of the accreditation program is legal compliance with the legislation covering the maintained biological resources and with the OECD Best Practice Guidelines for BRCs.

4.2.1.4 Microbial collections workflows

In general, microbial collections have the same workflow: deposit, cataloguing and supply.

- **Deposit**: where the mGR moves from *in situ* conditions to *ex situ* conditions. The focal point is the deposit form when the collections must gather and record all relevant information about the mGR and depositor. A minimum set of data is required to comply with technical and legal requirements. A number is assigned to the mGR and agreement is established as to what terms of use and transfer apply to the mGR.
- **Cataloguing:** involves recording the data from the deposit form and every data sheet for every mGR in the collection, as well as any information arising from the preserved material (i.e. quality control data). This information may be linked to other collections' catalogues or global facilities.
- **Supply**: a mGR provider transfers the material with the associated information linked to it. A MTA is set based on the information acquired at deposit and the intent of use.

Exchanging materials between collections is also a common practice, but it should be done as regular deposit/supply activities, with appropriate documentation. The most common bottlenecks are the validation of information given by depositors; the transport (delivery companies); border agents; and neglected quarantine rules. The TRUST workflow model for access and transfer mGRs (Fig. 11) and MIRRI Best Practice on ABS both facilitate compliance with the NP.

CABI is an international not-for-profit organization (with 48 members) that uses GR in its mission to improve people's lives by providing information and applying scientific expertise to solve problems in agriculture and the environment; CABI handles plant and animal GRs as well as mGRs. CABI works closely with the governments of its member countries, has had a policy on ABS since 1996 and has reviewed its practices post-Nagoya and post-EU Regulation. In its most recent policy statement[49], CABI states it will consider placing its collections on the EU registered collections list and comply with the requirements when they have been finally agreed.

Regarding tracking, CABI's current guidance obliges CABI staff to:

- Register all collections with CABI providing details of where collected, permit and other legal agreements, where the samples are held and their intended use;
- when handling the samples, add information to the database or record system where the samples are, who in CABI is handling them and what is being done with them;
- CABI will introduce reporting mechanisms back to National Authorities of provider countries and meet requirements for the ABSCH;

[49] CABI's Policy on Access and Benefit Sharing Compliance, 2016. For possible endorsement in July; currently being discussed with the National Focal Points in CABI's member countries, and kindly shared by D. Smith for this workshop.

- CABI will introduce reporting mechanisms back to National Authorities of provider countries and meet requirements for the ABSCH;
- Deposit samples of materials to be utilised in CABI collections;
- If there is a change in the use specified in the MAT, negotiate change of use with the National Authority of country of origin;
- Record generated data;
- Report Information on GR use and benefits shared to the country of origin, in line with MAT;
- Transfers to third parties is not permitted unless specifically stated in the MAT
- When receiving biological and GR from other providers, ensure the materials have been collected in compliance by asking for evidence e.g. the IRCC, ABS Clearing House UID, copy of PIC and MAT;
- When supplying material outside CABI, only supply if the MAT allows and only under an MTA laying down all conditions agreed in the MAT;

By following these best practices on tracking, CABI can monitor genetic resource use and enable timely and appropriate benefit-sharing and reporting to provider countries, including: lists of biological/genetic resources accessed and their use; relevant research and development results; and reports on sharing the benefits via partnerships, access and outcomes from CABI work. In addition, provider countries are included in CABI work programmes.

4.2.2 Natural History Museums

4.2.2.1 Museum utilisation of GRs

Natural history museums are often involved in the field collection and study of living organisms, but typically and traditionally the biological material that they maintain contains non-viable GR, used for non-commercial purposes, especially taxonomy. Much of the research that is conducted using museum specimens does not involve utilisation of GR. However, with the development of molecular techniques for taxonomy and phylogenetic analyses, museum specimens are increasingly used for DNA extraction, which is implicitly included under the current interpretation of 'utilisation' in the EU Regulation[50] and 'access' under the Brazilian law.

4.2.2.2 Post-Nagoya best practice tools: CETAF and GGBN packages

The Consortium of European Taxonomic Facilities (CETAF)[51], a taxonomic research network of 57 European natural science museums, natural history museums, botanical gardens and biodiversity research centres, has recently developed the CETAF Code of Conduct and Best Practices, in response to the Nagoya Protocol and the EU Regulation. CETAF members have committed to using the Code for biological material that is accessed (*acquired*) from a providing country after the entry into force of the NP, and are encouraged to apply the code, as far as reasonably possible, to all other biological material in their collections. An application has been made to consider the CETAF package as a best practice under the EU Regulation[52].

[50] There are informal discussions between some EU stakeholders and their Member States as to whether utilisation of GR for the purposes of identification and description should be subject to EU reporting obligations (due diligence declarations), if there are no commercial implications intended or emerging from the research. C. Lyal, pers. comm. to K. Davis, 22/05/2016.

[51] http://www.cetaf.org/; Code of Conduct available at http://cetaf.org/taxonomy/publications

[52] But there are not widespread moves by CETAF institutions to be included in the EU register of collections (pers. comm. with several CETAF institution representatives, April-May 2016)

The CETAF Code of Conduct contains provisions for the acquisition of biological material (with PIC and MAT where required), the utilisation of GR, the supply of biological material to third parties, the use of written agreements, ATK, benefit-sharing, curation and policies. It annexes (a) a Statement of Use of biological material, with institutional use information to provide when seeking PIC and other permits, (b) a more detailed Best Practice on ABS to guide institutions on the implementation of the Code of Conduct, (c) templates for three different MTAs to address loaned material, supplied/exchanged material and received material (where there is no supplier MTA), and (d) a non-commercial Data Use Statement for data released to the public domain via publications or sequence databases.

The CETAF Code of Conduct contains specific provisions related to tracking and monitoring terms and utilisation:

- Utilise GR on terms and conditions consistent with those under which they were accessed or otherwise acquired
- Acquire biological material (/ATK) using written agreements providing legal certainty and ensuring that there is a record of relevant documents such as PIC and MAT
- Supply biological material (/ATK) to third parties using written MTAs setting out the terms and conditions under which the biological material may be acquired, used and supplied and resulting benefits shared
- **Develop appropriate internal mechanisms and procedures** to
  - Record the terms and conditions under which biological material is accessed or otherwise acquired
  - Record relevant information on their utilisation of GR and benefits arising from that utilisation
  - Record supply of biological material to third parties permanently or on loan, including the terms and conditions of supply; and
  - Record when and how biological material passes permanently out of custodianship, including complete consumption of samples or disposal

The Code sets out desired and agreed outcomes, rather than prescribing particular mechanisms to meet the outcomes. The Best Practice provides more detail as to how the Code could be met, but uses language such as 'are advised' and 'ideally': participating institutions not required to follow the suggestions to the letter, though clearly EU institutions are required to comply with the EU regulation where their activities fall within its scope. The Best Practice guidance includes a section on record-keeping and data management, with information on the records that should be kept, including on the information needed for EU due diligence declarations and on transfers to third parties, benefits derived, deaccessioning, disposal and loss. It describes useful elements of a data management system:

- Means to discover rapidly what legal documents, requirements and restrictions are associated with a specimen or sample and ability to transfer this information to a user in another institutions;
- Means to discover rapidly all records on the use of biological material that entered the collections; this should include the establishment of unique identifiers (e.g. collection catalogue numbers) that allow tracking of specimens or samples;
- Means to link different data and information obtained from the use of biological material (such as DNA sequence information, images, or other digital representation) to the original sample or specimen;
- Means to retain all relevant records and legal information covering GR for an appropriate period of time.

A number of major museums and botanic gardens (including several CETAF members and Jardim Botânico do Rio de Janeiro) are now members of the Global Genome Biodiversity Network, an international network of institutions that share an interest in long-term preservation of genomic samples representing the diversity of non-human life[53]. The GGBN provides a platform, among other things, for the harmonisation of exchange and use of material in accordance with national and international legislation. GGBN has developed a Code of Conduct and Best Practices that shares most of its text with the CETAF package.

Museums and other such collections are at early stages of implementation of these Codes and Best Practices, though EU institutions are already responsible for making due diligence declarations under the EU Regulation. There are many practical challenges; although institutions may be able to comply with the essential requirements of ABS and the Code using basic tools already at their disposal, many are just now working out how to adapt their collections management systems to handle the ABS datasets necessary for compliance with the EU Regulation or to cope with other reporting requirements (especially those that extend beyond the scope of the original research projects for which biological material was acquired).

4.2.2.3 Natural History Museum workflows

A diagram illustrating some of the many possible routes of material into and out of a museum, with accompanying ABS documentation, and the points at which the EU regulation applies for EU museums, is shown in Fig. 11.

A 2004 Smithsonian case study[54] sets out general categories of tracking-relevant transactions common to many other museums:

- **Evaluation**: checking for paperwork - permits, agreements, and shipment documents; purpose of the transaction - permanent acquisition/temporary loan/disaggregation for and redistribution to other collections/education and display purposes;
- **Accessioning**: 'creation of an immediate and permanent record utilizing a control number for an object or group of objects added to the collection from the same source at the same time, and for which the museum has custody, right, or title'. An accession record includes the institutionally unique accession number, date of acquisition, type of acquisition (donation, exchange, field collection, etc), source; brief identification and description, provenance; and name of accessioning staff member. It is not a complete record of the object.
- **Cataloguing**: after examination and identification by a specialist during a research project - 'the creation of a full record, with descriptive detail, of all information about an object, assembly, or lot, cross-referenced to other records and files, and sometimes containing a photograph, sketch, film, sound, or other electronic data.'
- **Inventory**: 'the creation of an itemized list of objects, assemblies, and lots that identifies each object's or lot's physical location.'

[53] www.ggbn.org

[54] Hirsch L & Villegas AC. 2005. The Smithsonian Institution: the life of natural history museum specimens. Case study in Tobin B, Cunningham D & Watanabe K The feasibility, practicality and cost of a certificate of origin system for genetic resources: Preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme. UNEP/CBD/WG-ABS/3/INF/5.

- **Deaccessioning**: the removal of an accessioned object or group of objects from the museum's collection through a formal process for various reasons, such as damage, distribution to other institutions via open exchange or following identification, repatriation or return to owner.
- **Lending (loans or borrows)**: for study, identification, exhibition purposes.

Other steps can be added to this workflow, such as the publication of a collection's catalogued specimen data to GBIF or other data portals.

In practice, much material that comes to museums may never be accessioned, as accession is a serious legal step and national laws may make it difficult to deaccession unwanted, space- and resource-consuming material at a later stage; an alternative is to assign an **object entry**. Material that is accessioned may not be catalogued for many years (or ever), depending on the availability and interest of researchers and curators; specimens may be catalogued without ever being accessioned. There can be ambiguity over who owns a specimen or sample, especially when research associates bring 'their' material or visiting students leave excess material behind (CETAF guidance calls for policies to address and avoid such situations).

The accession or object entry record can provide a useful linking stage for ABS information (re. rights and obligations connected to a batch/lot of material from a particular provider via a particular access event and IRCC etc), using an institutionally unique identifier. An individual specimen's catalogue number is more likely carried onwards with the GR as it is sampled and extracted. Publications and GenBank sequences should be linked to catalogue numbers, though this is not always done. A current challenge for museums is to re-think workflows so that batch, accession-level ABS data are persistently linked with catalogued specimen-level data, so that rights are known before utilisation occurs, and also so that utilisation and supply events are recorded and can be linked all the way back to accession-level reporting obligations from original PIC and MAT.

Loans are of tremendous importance to the scientific community and so restrictive terms such as provider permission for loan or transfer can be significant impediments to biodiversity research, either preventing the specimen from being studied or requiring resource-intensive visits to many museums[55].

The Natural History Museum (London) uses KE Emu as its collections management database but, to meet the EU Regulation's and providers' reporting requirements, is developing a means to capture ABS information via a 'Rights' tab. The tab includes a Rights Number (identifier), Rights type (e.g. MoU, PIC, MAT, MTA, IRCC, collecting permit, export permit) and information on the person to whom the permit was issued; there are further fields for permit details and a 'restrictions apply' tick-box to alert users. The system, like an increasing number of collections management systems, enables the uploading of multimedia files such as

[55] The Smithsonian case study provides an example from Dr. Terry Erwin's 1993 collections in Ecuador: 1800 fogging events resulted in approximately 9 million specimens, which were sorted in Ecuador to class and order, and placed in jars containing 'restriction labels' referring to the MAT between the Smithsonian and Ecuador. These labels accompany every loan of the specimens and obligate loan recipients to the MAT conditions, and as identification to species progresses, the restriction labels move from samples to individual specimens. The Smithsonian returns 20 identified species per family to the Ecuadorian Politécnico University Museum (more could be sent if space and personnel allowed) and the rest stay at the Smithsonian or are supplied to other collections, always with the original MAT. Experts further sort and identify the collection and send subsets to other experts; the only remuneration for their time is generally being allowed to keep 2-3 specimens for their collections, when possible. By 2004, Dr. Erwin's collections from the fogging events had gone to 20 scientists in 17 institutions in 4 countries and many are still being used and identified.

PDFs of permits or other agreements. Rights records are linked to object entry records. Permits can also be entered for objects entering the museum on incoming loans and enquiries. Going forward, the NHM will be barcoding specimens individually, providing unique identifiers, to be linked to the object entry/accession record, which can be seen from the permit record, and a location record should also be attached so the specimen's location in the NHM can be discerned[56].

Many museums are only gradually digitising their older material; newer material and outgoing loans are more likely to be digitised. Several different systems may be in use at the same institution, so that linkage relies on staff manually transferring information between different systems as material is used and moved (e.g. for sequencing). This is not a trivial matter, given the amount of incoming and outgoing material and resource limitations at non-commercial institutions; the challenge is to capture ABS information as efficiently as possible upstream, when biological material is first acquired by the initial researchers, and then to find streamlined ways to communicate it to downstream users, so that their responsibilities are clear. Legislation and regulatory requirements for monitoring should be crafted in such a way that low-tech data management methods (such as spreadsheets, card indices and/or specimen labels) are useable, but institutions will also need to consider how to adapt and update their systems relevant to GR utilisation. Model contractual clauses, e.g. simple options for restrictions, would be extremely helpful for streamlining upstream ABS data entry and downstream user compliance.

4.2.3.1 Botanic garden utilisation of GRs

Botanic gardens are institutions holding documented collections of living plants for the purposes of scientific research, conservation, display and education[57]. They are highly diverse, including small gardens with living collections only (viable GR), and large, complex research and conservation-focussed institutions such as the Royal Botanic Gardens, Kew, which holds a mix of living and preserved specimens, containing viable and non-viable GR. A single living plant and/or its descendants in a botanic garden might be vouchered as a herbarium specimen, have its seeds stored in a conservation seed bank, have tissues taken for tissue culture or have DNA extracted and stored, or it might breed with another plant (some possibilities are illustrated in Fig. 12).

Though some botanic gardens may have links to the nursery trade and some may have partnerships with agricultural, pharmaceutical or cosmetics companies, in general EU and Brazilian gardens are most likely to acquire, utilise and supply the GR they hold for non-commercial purposes. The resources put towards tracking and monitoring in botanic gardens are generally proportional to the risk of misuse – herbarium collections (notwithstanding recent major international digitisation initiatives) are less likely to be comprehensively digitised compared to living plant or seed collections. However, as DNA analyses becomes more commonplace and as post-CBD and post-NP partnerships and obligations become more complex, herbaria are gradually re-evaluating their systems.

[56] C. Lyal, Natural History Museum, pers. comm. 20/05/2016
[57] Definition from the International Agenda for Botanic Gardens in Conservation: www.bgci.org/policy/international_agenda/.

4.2.3.2 Pre- and post-Nagoya best practice tools: the Principles on ABS, the International Plant Network (IPEN) and the CETAF/GGBN packages

Botanic gardens were among the first stakeholders to react to the CBD, and two of the ABS guidance tools in current use pre-date the NP[58]. Many CETAF and GGBN members are botanic gardens and some of them developed their ABS policies before the NP, using these earlier tools.

The pre-NP Pilot Project for Botanic Gardens[59] resulted in the Principles on Access to Genetic Resources and Benefit-Sharing and Common Policy Guidelines (CPG) to assist with their implementation. The one-page Principles cover acquisition, use and supply of GR, use of written agreements, curation, and benefit-sharing. Participating institutions must develop an institutional policy that covers their ABS-relevant activities and collections. The Principles are the direct precursor to the CETAF and GGBN Codes of Conduct and much of the wording is the same, including regarding the tracking of material and terms, but the Principles have not been updated post-Nagoya to cover utilisation rather than use, and more detail on ATK.

The International Plant Exchange Network (IPEN), also pre-NP, was developed by the Verband Botanischer Gärten (association of gardens in German-speaking countries) to provide more of a one-size-fits-all registration and tracking system to facilitate the exchange of living collections while respecting the CBD provisions. Unlike the Principles (and CETAF/GGBN codes), it does not require gardens to develop individual institutional policies, which were perceived as too cumbersome by many European institutions, especially for smaller gardens with few staff. IPEN member gardens abide by a common Code of Conduct that sets out responsibilities for acquisition, maintenance and supply of living plant material and associated benefit-sharing. The system establishes the 'IPEN number' – a unique identifier, assigned by the garden that first accessions a plant, that travels with the plant as it is propagated and exchanged between gardens, removing the need to use MTAs for each transaction. The general IPEN workflow is described below, though individual IPEN gardens may use quite different internal systems to implement the tracking. A Task Force provides for an internal compliance system, investigating possible infractions, and IPEN membership is subject to renewal[60].

4.2.3.3 Botanic garden workflows

Botanic gardens, like museums, use accession numbers, but the concept of 'accession' differs for living collections, where an accession typically refers to plant material (individual or group) of a single taxon and propagule type with identical or closely similar parentage acquired from one source at the same time. For tracking purposes in living collections, an accession is catalogued and assigned a unique identifier (number

[58] Information on the Principles on ABS and IPEN at www.bgci.org/policy/abs

[59] Conducted 1997-2000, funded by the UK Department for International Development and coordinated by Royal Botanic Gardens, Kew. The project brought together 28 highly diverse botanical institutions from 21 developing and developed countries (including the Jardim Botânico do Rio de Janeiro); several model agreements were also provided in an Explanatory Text. See Latorre, F., Williams, C., ten Kate, K. & Cheyne, P. (2001) Results of the Pilot Project for Botanic Gardens: Principles on Access to Genetic Resources and Benefit-Sharing, Common Policy Guidelines to assist with their implementation and Explanatory Text. Royal Botanic Gardens, Kew

[60] Biber-Klemm S, Davis K, Gautier L, Kiehn M & Martinez S. 2015. *Ex situ* collections of plants and how they adjust to ABS conditions. Ch. 15 in: Kamau EC, Winter G & Stoll P-T (eds) Research and Development on Genetic Resources: Public Domain Approaches in Implementing the Nagoya Protocol. Routledge Research in International Environmental Law series. Routledge, Abingdon, United Kingdom and New York, USA, pp. 208-225.

or code) associated with additional information[61]. Tracking of herbarium specimens or DNA extracts involves workflows similar to museum workflows.

New accessions entering the IPEN system, or any ABS-aware garden, are first assessed for compliance with the provider country's ABS legislation or regulatory requirements. Material that has restrictions on transfer and use can be flagged, but may not be suitable for exchange within IPEN.

The IPEN number contains four elements: (1) a code for the country of origin, (2) a code to indicate restrictions for transfer, (3) the first accessioning garden's code and (4) an identification number, the accession number of the garden. The first garden keeps full information on the accession, including scientific data, provenance and permits (the 'maximum documentation') for the plant and its descendants. Exchanges between IPEN members can take place with only the IPEN number ('minimum documentation'). Thus, the origins of IPEN accessions can easily be traced via the IPEN number, but there is no paper trail to allow tracking of the course of a GR between IPEN gardens. Exchanges with non-IPEN members, or material outside the scope of IPEN (herbarium specimens, DNA extracts) are covered by IPEN's standard non-commercial MTA. Commercial use is subject to the prospective user obtaining the provider country's PIC before any supply from the IPEN system.

An IPEN garden can use any system for internal tracking, as long as it can keep the IPEN number associated with the accession and comply with the terms. Gardens vary in their complexity. Missouri Botanical Garden, which has both endorsed the Principles and developed a Principles-based policy to cover its diverse activities *and* is an IPEN member, assigns and uses IPEN numbers as unique identifiers for all its living accessions, whether or not they are actually put into the IPEN system, and has developed a new Living Collections Management System (LCMS), with fields for data associated with permits and agreements and linkage of these data and scanned documents to appropriate accession records[62].

Other database systems commonly used by botanic gardens (whether IPEN members or not) include BG-BASE and Iris BG, both of which provide appropriate data fields for tracking source, permits and restrictions. BG-BASE now enables users to view documents in PDF instead of short-hand descriptions, and restrictions can be placed on incoming or outgoing material, allowing clients to centralise all their paper and electronic restrictions and MTAs, including IPEN, and to view restrictions via a click. BG-BASE is modular but this ABS information is available through all relevant parts including field collection notebooks, living accessions, propagation activities, quarantines, seed banks/DNA stores, herbarium specimens, outgoing shipments and requests for material[63].

IrisBG allows for the flagging of various restrictions for given taxa, accessions or accession item (such as a herbarium voucher or DNA extract); restrictions are recorded for the same taxa, accession and/or item, with more restrictive restrictions taking precedence. Approvals and agreements can be stored electronically and

[61] Aplin D. 2016. No Plant Collection without a Strategy or Policy. Ch. 3 in Gratzfeld J (ed) From Idea to Realisation: BGCI's Manual on Planning, Developing and Managing Botanic Gardens. Botanic Gardens Conservation International, Richmond, UK. Available at www.bgci.org/resources/2016-BGCI-botanic-garden-manual

[62] Pers. comm. Andrew Wyatt and Rebecca Sucher, Missouri Botanical Garden, October 2016, and Sucher R. 2013. Advances in living collections management. Proceedings of the 5th Global Botanic Gardens Congress, October 2013. Available at http://www.bgci.org/resources/3301/

[63] Pers. comm. Kerry Walter, BG-BASE (UK) Ltd., November 2015.

attached to relevant accessions, and users are alerted/prohibited from adding restricted plant material to an exchange. IrisBG can be used across different kinds of plant material (DNA extracts, tissue samples, etc.); it did not support storing DNA sequence data in 2015 but the developer was considering adding a DNA Lab Module to do so[64].

Kew, a large and complex institution, has developed its own systems. Staff training is a key component of Kew's tracking system and ABS policy[65] [66](based on the Principles): staff record, consult and transfer restrictions as material moves between Kew's collections and is transformed and utilised. The different curation systems in place for Kew's different collections are a function of scale (tens of thousands vs. hundreds of acquisitions/exchanges per year) and risk (specimen viability, provider concerns and expectations, and ability to implement any restrictions placed on material)[67].

Kew's herbarium receives and exchanges thousands of specimens annually. Large volumes of material and limited resources mean that Kew does not as a rule individually database all specimens and associate them with particular MTAs or other permissions as they arrive or leave. Specimens are individually databased if they are linked to current research and data-sharing projects, or type specimens sent on loan. Otherwise, material is databased on a batch basis. Batch information is not maintained with specimens unless there are special terms of acquisition, over and above the standard terms of non-commercialisation that apply across Kew's collections. If there are special terms, the batch number is kept with the specimens to enable cross-reference to the terms (if the specimens can be accepted – material may be refused if terms make curation in the general collection unfeasible). Standard terms are also set out in Kew MTAs, whether or not the material arrived with such restrictions. Herbarium sheets are physically annotated when material is removed for research. It is problematic to produce regular reports of how individual specimens are used or to maintain links between reports and individual specimens; instead Kew places emphasis on the development of long-term partnership projects that involve benefit-sharing and capacity-building, and shares benefits of research globally via publications and other information in the public domain.

In contrast, samples of live seeds collected for Kew's Millennium Seed Bank is accessioned individually into the Seed Bank Database (SBD) and assigned a unique serial number that links them to the terms of acquisition under Access and Benefit-Sharing Agreements (ABSAs) with provider country governments, as well as field data, lab-based processing and germination testing results, and information on supply to third parties. Collections and uses can thus be tracked from provider country to third parties. ABSAs sometimes restrict third party transfer, but compliance is feasible due to the SBD and the form of storage (in -20C voults away from visitors). MSB seeds are generally used for seed studies (e.g. germination tests, moisture relation tests, seed dormancy research and characterization), or may be grown to produce voucher herbarium specimens for taxonomic identification, or for public display. All such uses are recorded on the SBD. Herbarium specimens arising from seed collections are annotated with the relevant restrictions and cross-referenced with the seed collections and ABSA.

[64] Pers. comm. Havard Ostgaard, IrisBG, October 2015.
[65] Biber-Klemm et al. 2015.
[66] Based on the Principles; http://www.kew.org/sites/default/files/ABSPolicy.pdf
[67] Davis K, Middlemiss P, Paton A & Tenner C. 2005. The Royal Botanic Gardens, Kew: Herbarium and Millennium Seed Bank. Case study in Tobin B, Cunningham D & Watanabe K, The feasibility, practicality and cost of a certificate of origin system for genetic resources: Preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme. UNEP/CBD/WG-ABS/3/INF/5.

Standard Kew non-commercial MTAs are used for transfer and sampling of material from all of Kew's departments, though the terms vary slightly depending on the nature of the specimen – for example duplicate specimens (that Kew is permitted to give to third parties for non-commercial scientific use) have fewer restrictions, while DNA and living plants MTAs require users to keep 'retrievable records ', which could conceivably be used for tracking on a case-by-case as necessary.

4.2.4 Seed industry

4.2.4.1 Seed industry utilisation of GRs

The seed industry is a commercial sector that needs to be able to document and track the provenance and lineage of the plants that it researches, breeds, produces and markets for agricultural, horticultural and ornamental purposes. It also involves the use of biotechnological techniques (see 4.6, re. industrial biotechnology), and protects products using intellectual property rights such as patents for key technologies and traits, and plant breeders' rights for new varieties.

The GR concerned are obviously viable, and may derive from wild-collected resources, as well as landraces and commercial varieties. GR are used for conventional breeding programmes through the selection and development of germplasm (including through the use of molecular markers), for 'molecular-assisted' breeding using biotechnology, and for crop protection. Whole genome sequencing is rapidly becoming a fast and cheap way to find traits for breeding programmes[68]. The plant breeding process is illustrated at Fig. 14. Some of the plant GR that it utilises are within the scope of the International Treaty for Plant Genetic Resources in Food and Agriculture, and can be acquired via the Multilateral System under the terms of the SMTA for purposes of food and agriculture (some non-Annex 1 resources from certain e*x situ* collections can also be exchanged under the SMTA under Art. 15 of the ITPGRFA), subject to benefit-sharing, but many other species are not covered by the ITPGRFA, such as ornamental crops.

There has been major consolidation of the seed and agrochemical industries, driven by technological change and patents, but ornamental horticulture continues to be dominated by a larger number of small and medium-sized enterprises that rely on conventional breeding methods and mid-level technologies.[69]

4.2.4.2 Post-Nagoya best practices

Sectoral best practices are not yet available for the seed industry, though the European Seed Association (ESA) is working on a recommendations document, which might in future be submitted as a best practice.[70] The ESA represents several thousand seed businesses, ranging from cooperatives and family farms to companies listed on international stock exchanges.

The sector faces particular difficulties under variable and/or restrictive ABS measures because of the vast quantity of GRs needed in plant breeding, often originating from many different countries, to produce one variety (especially when using conventional techniques). Where the terms for different plants in a new

[68] Wynberg R. 2013. Bioscience at a Crossroads: Access and Benefit Sharing at a Time of Scientific, Technological and Industry Change: The Agricultural Sector. Secretariat of the Convention on Biological Diversity. Available at https://www.cbd.int/abs/policy-brief/default.shtml/.
[69] Ibid.
[70] Lisanne Boon, Rijk Zwaan, pers. comm. 23/05/2016

variety's ancestry contain restrictions and obligations to original providers, it is challenging for plant breeders to manage the final combination (Fig. 15)[71].

4.2.4.3 Seed industry workflow

As with other commercial sectors, it has been very difficult to find detailed information on the internal tracking mechanisms used by seed companies, likely for a range of reasons. The ESA's members vary widely in size and include many smaller companies that use low-tech methods for keeping track of breeding stock. Complying with post-Nagoya (and post-CBD) requirements and restrictions is a significant challenge for the smaller companies[72]. As with other sectors analysed, a wide range of tracking mechanisms is likely used.

Rijk Zwaan and KWS representatives were willing to share basic information on their ABS workflows. Rijk Zwaan is the world's fifth largest vegetable seed company, family-owned, and puts around 30% of its turnover into R&D[73]. It is active in multiple vegetable crops (with around 1000 varieties). KWS is an independent, family-owned German seed company focusing on crop breeding. The KWS group now has around 60 subsidiaries and associated companies, has a footprint in over 70 countries, invested 17.7% of its net sales in R&D and provides almost 400 new market approvals per year[74].

Rijk Zwaan breeders work with an electronic breeding administration[75]. All material used in the breeding program is included in that administration, so breeders have the option to include several details regarding the material, such as the date they acquired it and the location from which it was sourced. Rijk Zwaan has adopted a procedure whereby non-commercial material can only be used once it is cleared by the Legal Department. In such cases, the Legal Department provides the breeder with a 'Legal Department number,' which is then included in the breeding administration.

The Legal Department number stays attached to the specific resource to which it applies. The number will not be automatically visible for the breeding material made with that GR, but the breeding administration does include the option to perform a pedigree check. When such a check is performed, it displays a list of Legal Department numbers, attached to the genetic resources in the pedigree. These numbers correspond with the Legal Department files, making it easy for the Legal Department to see which agreements or conditions apply to specific material. A pedigree check is conducted at the moment a breeder wants to transfer material to a third party or at the moment a new variety is going to be commercialized. The company can then check the terms and conditions for third-party transfer, and for commercialisation of the new variety.

Possible restrictions include use only for evaluation trials, or only in a specific location; the company tries to avoid such limitations as much as possible. In some cases, they will accept them if that is the only way to use specific material, and then ensure that the breeders observe such limitations. The breeding administration uses a colour code system: green means that material can be freely used for research and breeding; orange means that there is a limitation with regard to the purpose of use or the location of use; red means that

[71] 'Access policy and legislation and transboundary commercial R&D from a plant breeding perspective,' presentation by Szonja Csörgő, European Seed Association, at workshop 'Access to Genetic Resources for in the EU,' London, February 25-26, 2016
[72] Szonja Csörgő, European Seed Association, pers. comm. 27/04/2016
[73] http://www.rijkzwaan.com/
[74] http://www.kws.com/aw/KWS/company-info/Company/~efhd/About-KWS/
[75] Lisanne Boon, Rijk Zwaan, pers. comm. 20/05/2016

material cannot be used at all. In principle, red material will not be present in the breeding program. When making crosses with GR, the colour code is transferred to the material resulting from the cross, and the most restrictive colour prevails; thus a cross between green and orange material will result in material with the orange colour code.

At KWS, the GR needed are identified and access information is collected using guidance from KWS's Legal intranet site. For access, KWS submits a template for approval of the provider country, with supporting documents; the access is approved or rejected, and if approved, the documents are stored locally for compliance. PDFs of completed documents are stored in the Legal database. The GR are then utilised within KWS; locally unique identifiers are used. The organisation would be easily capable of keeping information such as a registration number linked with material; as the representative informed us, 'KWS breeders are fastidious labellers and have tools to track and back track the use of all genetic resources, including the crossing histories.' If GR are shared with third parties, KWS first confirms compliance with sharing rights and restrictions, then records the transfer in the Legal database. Legal is copied on routine checkpoint documents (e.g. final product development) and the IRCC will be provided to the Legal database. The database can also generate reports for audits and on-the-spot checks. KWS also finds that the ESA recommendations towards a best practice are useful.[76]

4.2.5 Pharmaceutical sector

4.2.5.1 Pharmaceutical utilisation of GRs

According to Laird and Wynberg (2012)[77], as patents on profitable drugs are expiring, there are fewer new drug candidates in the pipeline, and the global industry in general is in transition. Demand for access to new genetic resources is mainly coming mainly from smaller players – small enterprises, government and academia – which are undertaking most of the natural product drug discovery, and then licensing to larger companies for development. They also note that rapid technological and scientific advances, in particular cheaper and easier genome sequencing, and functional genomics and proteomics, have affected the demand for access. Diversity that is found in companies' backyards and existing collections can be more easily mined as many genetic sequences are ubiquitous, so 'new' GR are less important. In addition, there has been a shift in the genetic resources being accessed – most research is now conducted on microorganisms. Field collections are smaller and more limited in scope now, and large compound libraries can be examined in new ways, so there is less incentive to conduct large-scale collection in areas of high endemicity.

4.2.5.2 Post-Nagoya best practice tools: International Federation of Pharmaceutical Manufactures and Associations (IFPMA) Guidelines

International research-based pharmaceutical companies support a positive approach to CBD implementation consistent with other international obligations and agreements. The IFPMA Guidelines[78] list best practices which should be followed by companies that engage in the acquisition and use of genetic resources. The

[76] Paul Olsen, KWS, pers. comm. 02/06/2016.
[77] Laird S & Wynberg R. 2012. Bioscience at a Crossroads: Implementing the Nagoya Protocol on Access and Benefit-Sharing in a Time of Scientific, Technological and Industry Change. The Secretariat of the Convention on Biological Diversity. Available at: https://www.cbd.int/abs/doc/protocol/factsheets/policy/ABSFactSheets-Pharma-web.pdf
[78] International Federation of Pharmaceutical Manufactures and Associations – IFPMA. Not currently available on the IFPMA website www.ifpma.org.

following provides an outline of industry best practices and steps that CBD members should take in order to provide the legal environment necessary to allow such best practices:
Industry Best Practices:

- To obtain prior informed consent (PIC) for the acquisition and use of GR controlled by a country/indigenous people and provided to the company in accordance with local law.
- In obtaining PIC, to disclose the intended nature and field of use of the GR.
- To gain necessary approval to remove materials found *in situ* and to enter into formal contractual benefit-sharing agreements reflecting the MAT on the use of the GR obtained through that removal. These agreements may contain conditions on permissible uses of the GR, transfer of the GR to third parties, and appropriate technical assistance and technology transfers.
- To avoid taking actions, in the course of use or commercialization of GR obtained as specified under these commitments that impede the traditional use of such GR.
- To agree that any disputes as to compliance with the clauses contained in formal contractual benefit-sharing agreements are dealt with through arbitration under international procedures or as otherwise agreeable between the parties.

IFPMA members strongly believe that implementing this agenda will significantly contribute in achieving to establish a practical access and benefit sharing environment conducive to value creation and equitable sharing of rewards through the clarification of major stakeholders' respective rights and responsibilities.

4.2.5.3 Pharmaceutical workflows

The pharmaceutical workflow is based on databases maintained by pharma companies and standard operational procedures implemented in their laboratories. In the case of Novartis[79], the workflow starts with the registration of the strain or plant (barcode or unique number) in the Novartis Pharma database (NP-NICE), including information on its origin (country) and provider. All information about the GR is recorded in the same database, including cultivation and/or extraction. The connection of biological results to genetic sources in the databases is made when the isolates of pure compounds receive a unique compound code (UCC). This code is registered in the central chemical database (WITCH) including its UCC, the reference to source from NP-NICE. A separate database (Pharon/Avalon) is used to store data on biological activities of compounds.

The use of multiple databases is necessary to prevent misuse of data, for confidentiality and for IP protection. The conditions for successful use of GR in Novartis Pharma research under CBD regulations are:

- Legal certainty:
  - national legislation with regulation of access rights, as necessary;
  - governmental entitlement of partner institute to negotiate sourcing contract;
  - inclusion of indigenous groups by collaboration partner or governments;
- Exclusivity/Transparency:
  - no exclusive access to biological resources of a country are necessary; however time-restricted exclusivity is important for research cooperation;
  - transferability of biological material to the laboratories of the industry partner;
  - implementation of transparency instruments to cover origin and location of genetic resources at industry partner;

[79] Petersen, F. Natural Products Unit, Novartis Pharma AG: Accessing microorganisms as genetic resources for natural products in drug discovery. IFPMA side event, WIPO IGC 23, Feb 5, 2013.

- PIC:
  - flexible definition of PIC terms due to complexity of drug discovery process and long time horizon;
  - coverage of broader range of research and development activities;
- Fair and equitable thinking:
  - open and flexible negotiations according to needs; mutual definition of CBD benefits by contract parties (significant differences of scientific expertise and know-how);
  - mechanisms to ensure equitable sharing of short, mid and long-term benefits with respect to risks and success rates
- Education:
  - the key for sustainable capacity building; one of the main motivations to contact Novartis' NP group;
  - definition by collaboration partners and adapted to specific needs and capabilities on site;
- IP and financial compensation:
  - transparent regulation of ownership of inventions; resulting patents filed according to international patent law;
    licence and royalty payments.

4.2.6 Industrial biotechnology

4.2.6.1 Industrial biotechnology utilisation of GRs

Biotechnology, defined in and covered by the CBD and the Nagoya Protocol, includes technologies and activities across a range of sectors, including healthcare biotechnology, agricultural biotechnology (which includes modern plant breeding techniques including genetic modification) and industrial biotechnology. This section will focus on the latter, which uses microorganisms and enzymes to made products (such as bread, cosmetics, detergent, polyesters, packaging and plastics) from biomass such as agricultural feedstocks and wood pulp, as well as to solve problems, e.g. via bioremediation.

Microorganisms, the source of industrial biotech products, are viable GR (and some products may be just a few steps from the original GR), while enzymes are clearly derivatives of GR, so industrial biotech handles a range of materials from an ABS perspective.

In her review of industrial biotech, Laird (2013)[80] reflects that research and development in this sector is difficult to track: 'the processes and products are often neither sold nor patented, and are instead developed and used within the same company, and are protected through secrecy; many companies are privately-owned and so do not disclose their practices to shareholders; and industrial biotechnology is very lightly regulated by most governments. Few governments collect data on this sector, and most are struggling to come to terms with the novelty and implications of its technology.'

[80] Laird S. 2013. Bioscience at a Crossroads: Access and Benefit Sharing at a Time of Scientific, Technological and Industry Change: Industrial Biotechnology. Secretariat of the Convention on Biological Diversity. Available at https://www.cbd.int/abs/policy-brief/default.shtml/

Laird points out that companies can increasingly access genetic information from sequence databases rather than from physical transfer, and can improve or create new enzymes via synthetic biology. However this sector does have still an interest in novel micro-organisms, which they may source from internal and external collections, from their own backyards (many micro-organisms and genetic sequences are ubiquitous), and from field collections overseas, with special interest in extreme or species-diverse environments or other habitats that might contain niches of interest (ten Kate & Laird 1999)[81]

4.2.6.2 Pre- and post-Nagoya best practices

Laird also notes that companies vary hugely in their awareness of the CBD and the Nagoya Protocol. Those companies that source micro-organisms from microbial collections that are part of ABS networks, compliant with ABS and using MTAs to supply samples might be expected to be more ABS-aware (though see below, re. Novozymes A/S experience). A wide range of benefits can be shared in the course of obtaining access to samples and collaborating with scientists, although opportunities for benefit-sharing with original providers are rarer for companies that exclusively source from collections or close to home[82].

Certain companies, notably Novozymes A/S (founded in 2000 in a demerger from Novo Nordisk) have been implementing ABS best practices for many years. Novo Nordisk set out 'Guiding principles for Novo Nordisk's implementation of the Convention' for both its healthcare and enzyme businesses in 1997 and reported on its progress in the company's Environmental and Bioethics Report in 1998, identifying two main requirements for successful cooperation between providers and users of GR: an effective system for establishing PIC without too much bureaucracy, and for users to be able to identify whose PIC is needed. The target for 1999 was for all relevant patent applications and publications from 1999 onwards to disclose the country of origin of genetic material and the target for 1999-2000 was to develop procedures for monitoring the implementation of the company requirements on the use of and access to GRs.
Examples of benefits shared with providers of GR for the development of a new enzyme included: support to establish and maintain culture collections; introduction to isolation and preservation techniques; contact with taxonomists to identify microbial GR, contact with expert scientists, training (in safety procedures, sterile techiques, enzyme assay techniques and moleulcar biology), technology and assistance with and co-authorship of scientific papers[83].

The overall guidelines at Novozymes A/S are[84]:

- Novozymes A/S respects and strives to be in compliance with the Convention on Biological Diversity and the Nagoya protocol.
- Novozymes A/S needs clear condition for commercial utilization of GR before starting development
- Novozymes A/S needs legal certainty for utilisation
- User compliance article 4.5 (EU Regulation): When the information in their possession is insufficient or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation.

On the EU side the process for developing sectoral guidelines has just begun, with a meeting in mid-June 2016. No EU best sectoral practices have been developed yet.

[81] Ten Kate K & Laird SA. 1999. The commercial use of biodiversity: access to genetic resources and benefit-sharing.
[82] Ibid.
[83] Ibid.
[84] Søren Flensted Lassen, Novozymes A/S, pers. comm. 23-24/05/2016

4.2.6.3 Industrial biotechnology workflow[85]

As discussed, it is difficult to find out information about internal workflows from commercial companies, but traceability is important. Timely availability of information to document CBD/ABS compliance is extremely important so products going into the market are not limited or hindered.

In the experience of Novozymes A/S, few organisations dealing with GR can deliver the necessary ABS information as clearly as needed, so it is preferred to conduct *in situ* environmental sampling under the clear authority of the competent authorities of a country, with full legal certainty for utilisation. In that way Novozymes A/S can know up front if the information that it needs to seek, keep and transfer to subsequent users can be made available. ATK is not used.

To comply with the EU Regulation (and Nagoya), the company keeps records of the data including precise GPS coordinates for the environmental sampling location, and PIC (or other access permits, depending on local legislation) and MAT are clarified before sampling, including rights and terms for commercialisation. This information is linked throughout the further development on the samples and/or derivatives of the sample to ensure traceability of the product. An in-house system is used to keep track of processes. Each step in the development has its own unique identifier that is linked both back and forth in the development chain.

4.3 Other traceability systems and tools

Several other systems in use, or being further developed, by various natural products sectors might have potential for the future tracking (and/or verification) of GR and ABS information. We will not detail them here but participants may wish to explore them further and bring them into the discussion.

4.3.1 Chain-of-custody certification

Chain-of-custody certification is becoming increasingly important for several sectors using natural resources, such as the sustainable forestry industry and natural products companies. Chain of custody is basically an inventory tracking and control system; companies that achieve certification have met the requirement of a standard (such as the Forest Stewardship Council and Programme for the Endorsement of Forestry Certification standards for forestry[86]), and have been audited by an accredited certification body.

In particular, The FairWild Standard (FWS)[87], which covers the sustainable use of wild-collected plants in trade, contains principles that notably include ABS-relevant elements:

- complying with laws, regulations and agreements (Principle 3) – documentation to demonstrate implementation includes collecting permits, if required, trade/export permits or registration, and proof of tenure and resource access rights;
- respecting customary rights and benefit-sharing (Principle 4) – documentation includes ABS agreements if relevant, and documentation of the process to achieve such agreements.

[85] Ibid.
[86] https://ic.fsc.org; www.pefc.org
[87] http://www.fairwild.org/

4.3.2 DNA sequencing for geographical origin

DNA barcoding will be well known to workshop participants as a tool that is increasingly valuable for traceability in food systems and industrial pipelines as well as for biodiversity research. 'Traditional' DNA barcoding distinguishes organisms at the species level, though there is some potential for barcode markers to be used for intraspecific differentiation where there is considerable phylogeographic divergence within a given species. As Next Generation Sequencing and full genome sequencing studies begin to populate sequence databases with information from other regions beyond the species barcode region(s), and as an ever more comprehensive reference dataset is developed for every species, the potential for intraspecific geographical traceability via DNA sequencing grows - but it still is a long way from being a strong source of evidence that would stand up in a theoretical court[88].

4.3.3 Fourier Transform Infrared Spectrophotometry (FTIR)

This technique is beginning to demonstrate potential for geographical traceability[89], in combination with chemometrics tools, providing reliable authentication in a rapid and inexpensive way. It is being developed in the natural and agricultural food products sectors for quality and traceability control[90].

4.3.4 MyEcoCost

MyEcoCost was a European Union FP7 funded project[91] to develop the concept of electronically attaching Chain of Custody information to financial transactions, to allow full traceability from raw materials to finished product. It was aimed at creating a product carbon footprint, but could be adapted to facilitate traceability[92], as it enables the passing of data from supplier to customer through a whole value chain.

4.3.5 Blockchain concept

The blockchain is a new concept currently being explored in the financial world; it might have some future relevance for natural and genetic resource traceability systems and chain of custody verification[93]. It involves protecting information via a decentralised network, with data stored on many computers, each in direct contact with all the other computers on the network, which makes the system efficient and very resistant to manipulation compared to traditional databases with centralised control. It may provide a new, secure means of registering and transferring information on rights, obligations and GR information between providers and users all along a supply chain.

5. PRELIMINARY ANALYSIS

We have identified the monitoring components of the Nagoya Protocol and described how the EU Regulation and Brazilian Law will monitor certain stages of utilisation. We have also noted some potential gaps in the system (e.g. transfer of materials between non-users, and then to users in non-Nagoya Parties) and areas of possible confusion (e.g. different use of terms). The EU Regulation will not apply to Brazilian

[88] Alex Borisenko, Biodiversity Institute of Ontario, pers. comm. 24/05/2016
[89] Paul Wilkin, RBG Kew, pers. comm. 23/05/2016
[90] Cozzolino D. 2012. Recent trends on the use of infrared spectroscopy to race and authenticate natural and agricultural food products. Applied Spectroscopy Reviews 47(7)
[91] http://cordis.europa.eu/project/rcn/105615_en.html
[92] Andrew Jenkins, Walgreen Boots Alliance, pers. comm. 19/05/2016
[93] Ibid.

material until Brazil becomes Party to the Nagoya Protocol, though of course EU users are required to comply with Brazilian terms they agree to via permits and MTAs.

When EU and Brazilian systems do connect, the governmental systems will not result in the reporting of all stages of utilization, and will not enable the location of material as it moves around, but – in combination with other Nagoya Parties' monitoring systems – should enable the notification of providers when a commercial product makes it to market.

Users need tracking systems in order to comply with the monitoring requirements. In all sectors we examined, we have found tracking systems, though they vary greatly in sophistication. Microbial collections that use the OECD Best Practice for BRCs, MIRRI ABS best practices and/or the TRUST model, clearly have the most clearly harmonised and functional tracking systems, allowing for both tracking the course of GRs and tracing their origin. Particularly taking in consideration the conformity assessment system implemented in Brazilian service collections, this approach could build a solid bridge between EU and Brazil in terms of mGR exchange. Despite the diversity of uses of mGR, but perhaps also because of their importance to a range of commercial sectors and the scrutiny that they receive for biosecurity purposes, global data coordination and ABS tracking is within reach with greater dissemination of these best practices.

We have found it difficult to obtain detailed information from commercial companies and sectoral associations about the nature of their tracking and monitoring systems. This reticence may be due to several factors, including concerns about possible gaps in compliance, especially where sectoral associations include players with lower ABS awareness and capacity, and concerns about sharing information on proprietary systems in a competitive environment. For (predominantly) non-commercial museums and botanic gardens, there is rather more transparency regarding internal practices, although they also have practical concerns regarding new requirements. Their current practices generally should allow tracing back to origin and providers' terms (although the process may be cumbersome), but only limited tracking of a GR's movements and uses is possible, especially after GR are supplied to third parties.

A previous study of genetic resource tracking and monitoring systems (Tobin et al 2005)[94] to explore the feasibility, practicality and cost of a certificate system, determined that different collections' internal management systems could be used, as long as the relevant data regarding any certificate are available and are **recorded at entry and at exit**, to ensure that what goes out can be linked to what came in: 'Any requirements relating to internal record keeping associated with biological and genetic resources should be minimal and only such as is necessary to ensure that the maintenance, use and transfer of resources to third parties is made in accordance with the terms and conditions under which they were obtained'. Especially for resource-challenged collections, keeping the costs of monitoring down enables more resources to be put towards research and cooperation, thus generating more scientific benefits that can be shared, such data and tools to support practical biodiversity conservation.

Using various policy frameworks and data management systems, the collections and companies we examined are capable of ensuring that terms and conditions are honoured, and should all be capable of handling IRCC numbers and CAR numbers when they are linked to material.

[94] Tobin B, Cunningham D & Watanabe K. 2005. The feasibility, practicality and cost of a certificate of origin system for genetic resources: Preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme. UNEP/CBD/WG-ABS/3/INF/5.

Although persistent, globally unique identifiers would be ideal for long-term ABS tracking, they are not currently used in most of the sectors examined. Internal locally unique identifiers are more common, or institutionally unique identifiers, but these still allow for tracking and monitoring. This situation may gradually change and new identifiers may be adopted as institutions move towards integrating more and more in global databases such as GBIF.

IRCCs (with their unique identifiers), or comparably trackable access documents such as CARs, should prove much easier to record and track than a multiplicity of paper documents attesting to legal access. However, as noted earlier (section 3), there are other permits that also apply. National systems that can share information, and perhaps coordinate different permissions (including research, collecting and export permits) to produce a single trackable document, would greatly facilitate the linkage of GR with all provider terms.

In informal discussions, it is the variable number and kind of documents – not necessarily access permits – that is repeatedly raised as one of the biggest challenges when acquiring and exchanging material. For shipping, many procedures must be followed, many forms need to be filled and a lot of time is required. The requirements and agencies involved have different technical competences and purposes, but they should work together towards a less cumbersome process, for example, by exchanging the information they hold through an integrated system that allows authorisation and documents to be issued in only one place. The amount of paperwork seems unnecessary, costly and time-consuming; some steps should be simplified to reduce the time and costs needed.

On the 'user' end, researchers and curators are not sure how to evaluate documentation for incoming specimens, to ensure that there is legal and ethical certainty. An important bridge between Brazil and EU could be built if all people dealing with the handling, shipping and receiving of specimens had more clarity as to what documents or registrations were needed for particular situations.

It is not evident from current practices that Brazilian authorities will be able to know where all Brazilian material resides or exactly how it is being used, but as awareness is built and internal tracking practices improve, there will be greater traceability back to the provider for a range of results such as publications and DNA sequences. Post-Nagoya best practices such as the CETAF code of conduct are just now being disseminated and implemented, and collections that were previously relatively unaware are now waking up to the necessity for ABS action, prompted by the need to comply with the EU regulation and other new laws and the scrutiny of new competent authorities that are also adjusting to their roles. The risks of legal uncertainty are traditionally lower in collections used almost exclusively for non-commercial purposes, and they may have little or no legal resources to help them understand or navigate the international ABS environment. The new best practice tools will help. From the Brazilian end, the ability to track and trace material could be improved if users were required to deposit subsamples in CGen-recognised biological collections before shipping GR abroad. In the absence of such a requirement in Law 13.123, codes of conduct and/or best practice guidelines should, for Brazilian collections, emphasise the need for such deposits.

The concept of viral licencing (a licence that imposes the same terms on derived works/products[95]; as suggested in a previous analysis, Annex 1) might potentially work for 'networks of compliance', especially for users that are implementing EU-recognised best practices, for example museums that have implemented the CETAF code of conduct, when/if the CETAF package is officially accepted. However, awareness of ABS must be significantly raised so that any terms that are accepted and transmitted 'virally' are properly understood and complied with as necessary.

Ability to track is only part of the picture; ability to comply with the tracked terms is another. Certain restrictions may be unsuitable for certain types of scientific exchange (such as provider PIC for museum loans) and plant breeding (a multiplicity of different authorisations and non-negotiable terms from different providers). Harmonised systems (such as IPEN) facilitate tracking and exchange but run to a halt when there are more restrictions, especially those such as reporting obligations that extend past the life of the initial project for which the GR were collected, and the collaborative relationships between the first researchers.

Several of the recommendations in the previous analysis (Annex 1), perhaps because they were developed with a focus on the pharmaceutical pipeline, do not in this analysis appear to be very practical or cost-effective for *ex situ* collections that are primarily used for non-commercial research. In particular, requirements that require reporting to CGen on every use and permission for transfer of material are problematic for museum and botanic garden collections. This issue and possible solutions could be productively discussed during the workshop.

EU reporting obligations to competent authorities should create less difficulty than long-term reporting obligations from the provider, although EU reporting does not convey the detailed research results or specimen location information that the provider may be seeking. However, together, the implementation of the EU regulation and the final product notification stage of the Brazilian law might argue for fewer reporting obligations at other stages, e.g. via MTAs, as there will be a much higher likelihood of downstream commercial development being notified to Brazilian authorities.

Transfer restrictions may be easier to comply with, as specimens/samples should be able to be flagged using standardised, easily-understandable options for database fields and/or labels, but such restrictions have the negative effect of greatly reducing research opportunities and the scientific value of specimens. There is always the concern that requests for PIC to transfer will receive no reply rather than a negative or positive reply, creating a limbo situation.

A requirement to collaborate with a Brazilian institution for access to *in situ* Brazilian resources does not appear to be a significant barrier to research; EU institutions need to have sufficient resources to support a more in-depth partnership, but such collaborations will inevitably lead to more effective and practical sharing of scientific opportunities and data. Better, clearer coordination between the multiplicity of different involved agencies would foster closer scientific collaboration and exploration.

Our examination of legal frameworks and sectoral tracking has thrown up a number of questions (set out below) that can be considered during the workshop.

[95] An example of a viral licence is the Creative Commons Attribute-ShareAlike (CC-BY-SA), which says 'if you alter, transform or build upon this work, you may distribute the resulting work only under the same or similar license to this one.' http://opendefinition.org/licenses/cc-by-sa/

6. QUESTIONS

What is the purpose of monitoring and tracking GR?

- What is important for Brazil to know (and potentially control): (a) where its GR are held, (b) how they are being utilised at all stages, (c) when utilisation produces commercial results to ensure benefits are shared, or (d)…?

What are the characteristics of a workable tracking system?

- What level and kind of tracking is needed for compliance with EU and Brazilian monitoring requirements?
- What level and kind of tracking is feasible, acceptable and cost-effective for users?
- What could the simplest system that would meet Nagoya/EU/Brazil requirements look like?
- Of the different tracking systems in current use, what are the shareable features and properties that are effective, practical and acceptable to providers and users?
- What interactions/communications are needed on the Brazilian side, between what entities, to enable monitoring and tracking *and* facilitate utilisation and benefit-generation?

What identifiers are needed for ABS to work?

- Do identifiers in tracking systems need to be persistent, or globally unique, in order for the global ABS system to work?
- Do the IRCC and the Brazilian Certificate of Access Regularity provide workable identifiers for ABS terms, to keep them linked with material, via MTAs etc.? Are additional permits+identifiers needed?
- What granularity does an identifier require in order to achieve ABS objectives? Does a GR need to be described minutely in order to be tracked, and new identifiers given to derivatives?
- Why aren't GUIDs used more extensively by more sectors - and could they be developed?

How can model contractual clauses bridge the gaps between the Brazilian law and EU regulation?

- What model MTA clauses would facilitate sectoral tracking?
- Are MTAs enough to ensure that registration numbers and terms travel with genetic resources, and that downstream commercial benefits will be shared with Brazil?
- Why have MTAs been problematic to implement in Brazil and how can this be improved under the new system?
- Can Brazilian and EU governments and stakeholders develop standardised options that can be more easily incorporated in MTAs and sectoral data management systems (& best practices)?
- How to ensure there are not multiple MTAs from multiple sources (e.g. different regulatory agencies)

What is the role of best practice in the tracking/monitoring context?

- Should/can best practice be imposed?
- Are models or standards more effective?
- What are the barriers to implementing best practices?
- Will/should the Brazilian system allow for risk-based approaches in collections outside Brazil?

- Should Brazilian and EU authorities regard the non-commercial utilisation of preserved collections as low risk?
- Should preserved collections be treated in a different manner to living collections, for ABS?

What level of tracking is conducted at Brazilian *ex situ* collections?

- Do they share collections management systems?
- Do they share information on tools for ABS compliance?

How are subsamples currently linked to Brazilian permits?

- What identifiers are used for the subsamples?
- Is sequence data used? Or is the assumption that DNA could be sequenced if necessary? Or might other traceability tools be used?
- How are associated taxa handled, e.g. symbionts and pathogens?

What other measures are needed to facilitate exchange and utilisation?

- How can Brazil and the EU clarify the conditions for legal acquisition and shipment, beyond access?
- What interactions/communications are needed on the Brazilian side, between what entities, to enable monitoring and tracking *and* facilitate utilisation and benefit-generation?
- What do Customs/police/postal authorities need to know and see?

Table 1: Key terms used in Nagoya Protocol, EU Regulation 511/2014 and Implementing Regulation 2015/1866, and Brazil Law 13.123/2016.

Term (English)	Term (Português)	**Nagoya Protocol**	**EU Regulation 511/2014**	**Brazil Law 13.123**
Genetic material	Material genético	CBD definition: any material of plant, animal, microbial or other origin containing functional units of heredity	Any material of plant, animal, microbial or other origin containing functional units of heredity	Not employed
Genetic resources (GR)	Recursos genéticos	Genetic material of actual or potential value	Genetic material of actual or potential value	Not employed
Genetic heritage (GH)	Patrimônio genético	Not employed	Not employed	Genetic information of plant, animal and microbial species or otherwise, 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 beings
Derivative	Derivados	Naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity	NP definition, in preamble only (In draft scope guidance document: 'access to derivatives is covered when it also includes genetic resources for utilisation, i.e. when access to a derivative is combined with access to a genetic resource from which that derivative was or is obtained)	Employed in definition of GH

Traditional knowledge associated with genetic resources	Conhecimento tradicional associado ao patrimônio genético	Not defined	Traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the genetic resources	Information or practices of indigenous peoples, traditional community or traditional farmer on the properties or uses (direct or indirect) associated with the GH
Acquisition	Coleta	Not employed	Employed in definition of access	Obtaining animal, plant or microbial wild organism, either by removing the individual from its natural habitat whether by collection of biological samples[96]
Access	Acesso	Not defined	Acquisition of GR or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol	Research or technological development carried out on GH sample
Utilisation of genetic resources	Uso do pstrimônio genético	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	NP definition	Utilisation is considered access
User	Usuário	Not defined	Natural or legal person that utilises GR or ATK (Draft guidance: *not* a person/entity who only transfers material or who only commercialises products based on utilisation)	Natural or legal person that performs access to GH or ATK or economically exploits the finished product or reproductive material originated from GH or ATK access

[96] For further information, see Normative Instruction No. 3/2014 – ICMBIO

Intermediate product	Produto intermediário	Not employed	Not employed	Product whose nature is the use in the production chain, which will aggregate it in its productive processes as an input, excipient and raw materials for the development of another intermediate product or finished product
Finished product	Produto acabado	Not employed	Not employed	Product originated from GH or ATK access whose 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 natural or legal person
Result of the utilisation	Resultado da utilização	Not employed	Products, precursors or predecessors to a product, as well as parts of products to be incorporated into a final product, blueprints or designs, based on which manufacturing and production could be carried out without further utilisation of the GR and ATK	Not employed

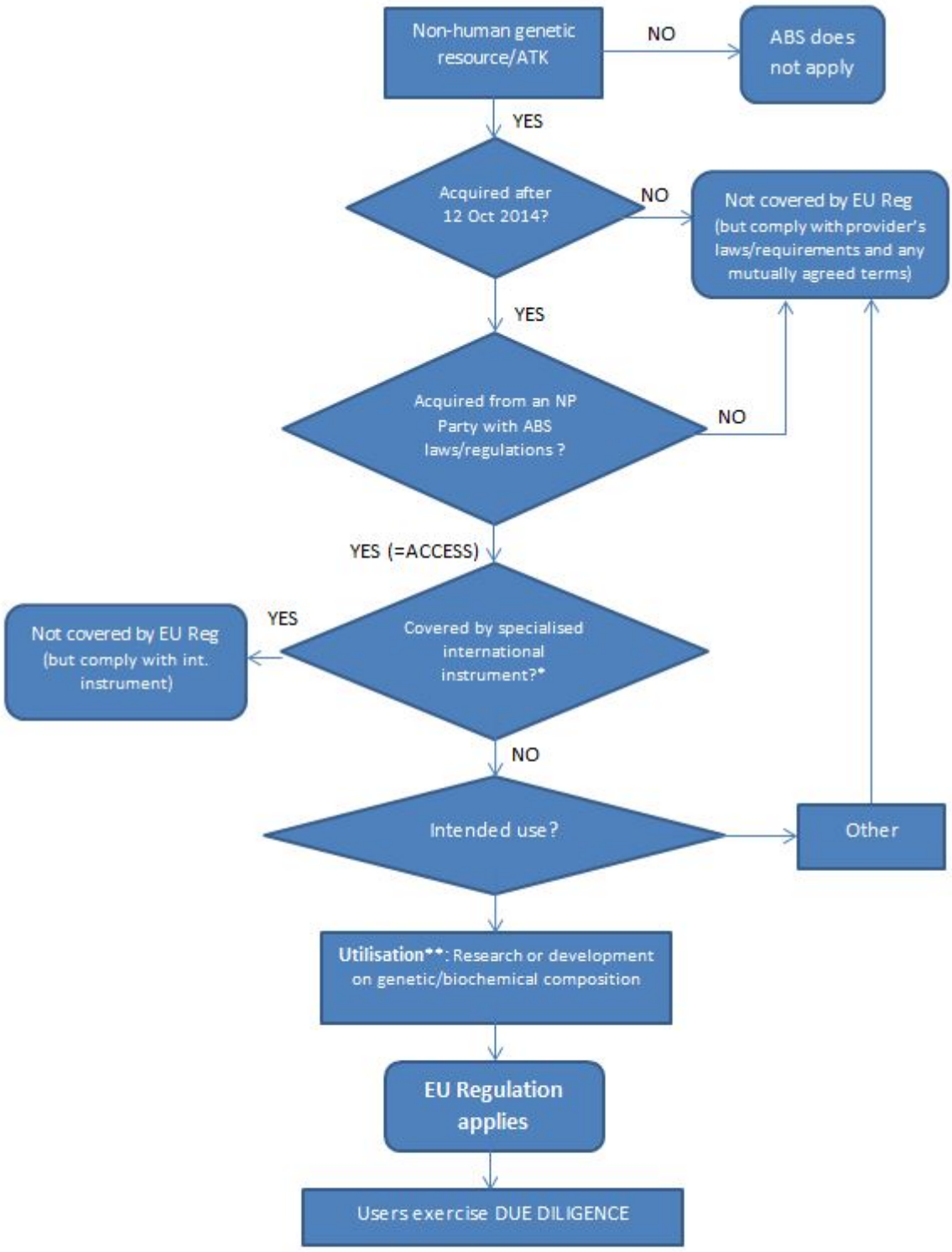
Placing on the Union market	Colocação no mercado	Not employed	The first making available of product developed via utilisation of GR and ATK on the Union market, where making available means the supply by any means, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. Placing on the market does not include pre-commercial trials, including clinical, field or pest resistance trials, nor the making available of unauthorised medicinal products in order to provide treatment options for individual patients or groups of patients	Not employed
Internationally Recognized Certificate of Compliance (IRCC)	Certificado de Conformidade Internacionalmente Reconhecido/Certificado de Regularidade de Acesso	A permit or its equivalent issued in accordance with Article 6(3)(e) and made available to the ABS-CH… as evidence of the decision to grant PIC and of the establishment of MAT, notified to the ABS-CH… as required by domestic ABS legislation or regulatory requirements of the Party providing PIC	A permit or its equivalent issued at the time of access as evidence that the GR it covers has been accessed in accordance with the decision to grant PIC, and that MAT have been established for the user and the utilisation specified therein by a competent authority in accordance with Article 6(3)(e) and Article 13(2) of the NP, that is made available to the ABS-CH established under Article 14(1) of that Protocol	Certificate of Access Regularity (CAR): administrative act by which the competent authority declares that access to GH or ATK complies with the requirements of this Law.

Checkpoint		Not defined. A body with functions relevant to the utilisation of GR or to the collection of relevant information [at…], that collects or receives relevant information related to PIC, the source of the GR, the establishment of MAT, and/or to the utilisation of GR, as appropriate, and provides such information to relevant national authorities, to the Party providing PIC and to the ABS-CH, as appropriate	Competent authority: the body responsible for the application of the Regulation	Not defined, but CGEN fills this role

Registered collection	Coleção credenciada	Not employed	Not defined, but criteria established for inclusion in the EU register of collections: collection (or part of a collection) that has demonstrated its capacity to: apply standardised procedures for exchanging samples of GR and related information with other collections and for supplying samples of GR[…] to 3rd persons for utilisation in line with the CBD and NP; supply GR[…]to third persons for their utilisation only with documentation providing evidence that the GR[…]were accessed in accordance with applicable ABS legislation/reg. requirements and MAT; keep records of all samples… supplied to 3rd persons for their utilisation; establish/use unique identifiers, where possible, for samples of GR[…]supplied to 3rd persons; use appropriate tracking and monitoring tools for exchanging samples of GR[…] with other collections.	Not defined, but the law provides the registration of national institution which maintains a ex situ collection of samples containing genetic heritage.
Material Transfer Agreement (MTA)	Termo de Transferência de Material (TTM)	Not employed. (Reference is made to mutually agreed terms throughout, and model contractual clauses for MAT in Article 19)	Only employed in the context of the ITPGRFA's Standard MTA	Material Transfer Term: instrument firmed between sender and receiver for shipping abroad one or more samples containing the GH accessed or available for access, indicating, if applicable, if there was ATK access and establishing the benefit sharing commitment.

Figures

Figure 1: Accessing and utilising GR under EU Regulation 511/2014: Does the regulation apply?



*Such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the WHO Pandemic Influenza Preparedness Framework; including **specified use**: e.g. food crop on ITPGRFA Annex I accessed from Party to ITPGRFA, **used for food/agriculture purposes**

**Including basic research

Figure 2: Accessing and utilising GR under EU Regulation 511/2014: Due diligence requirements.

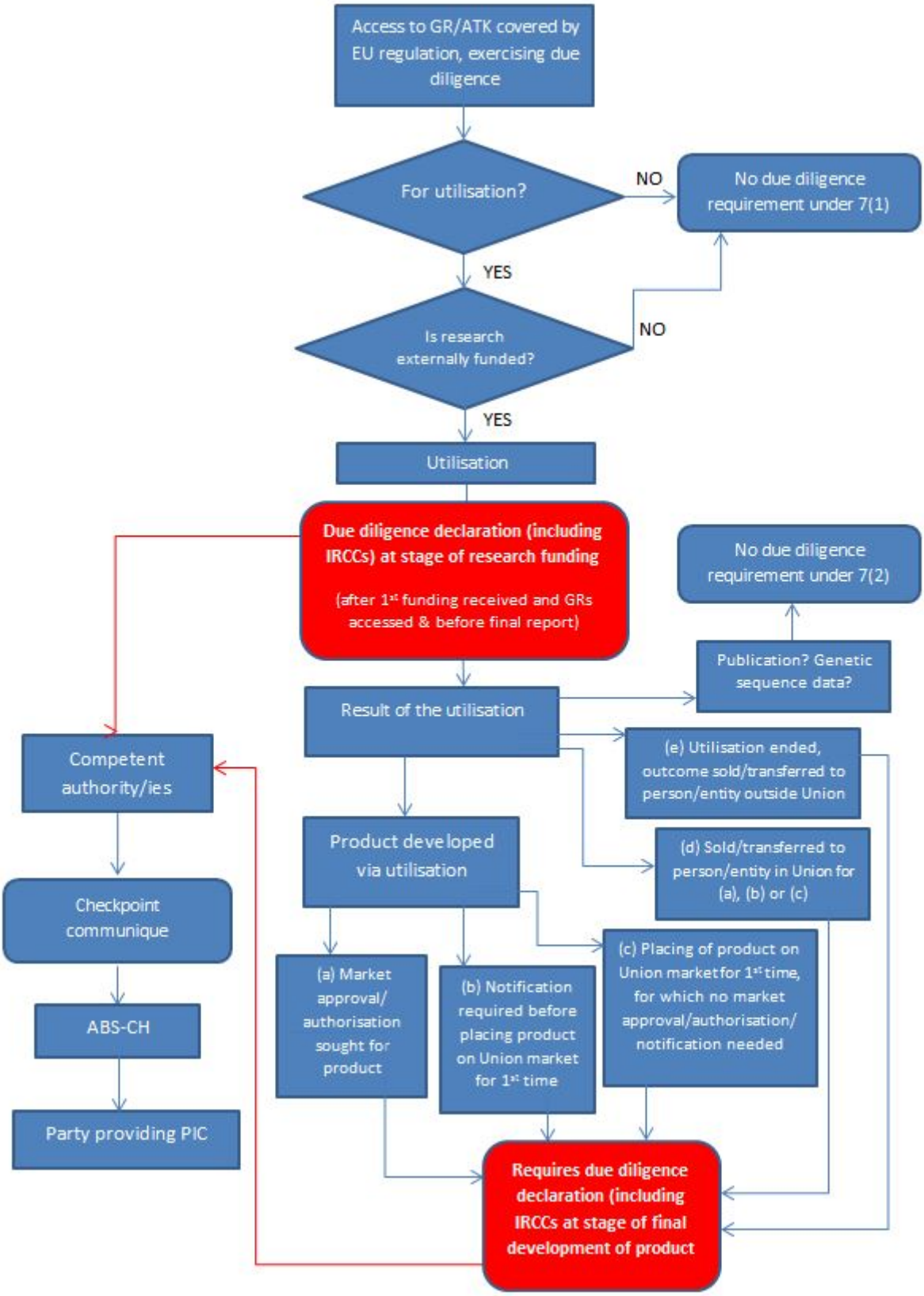
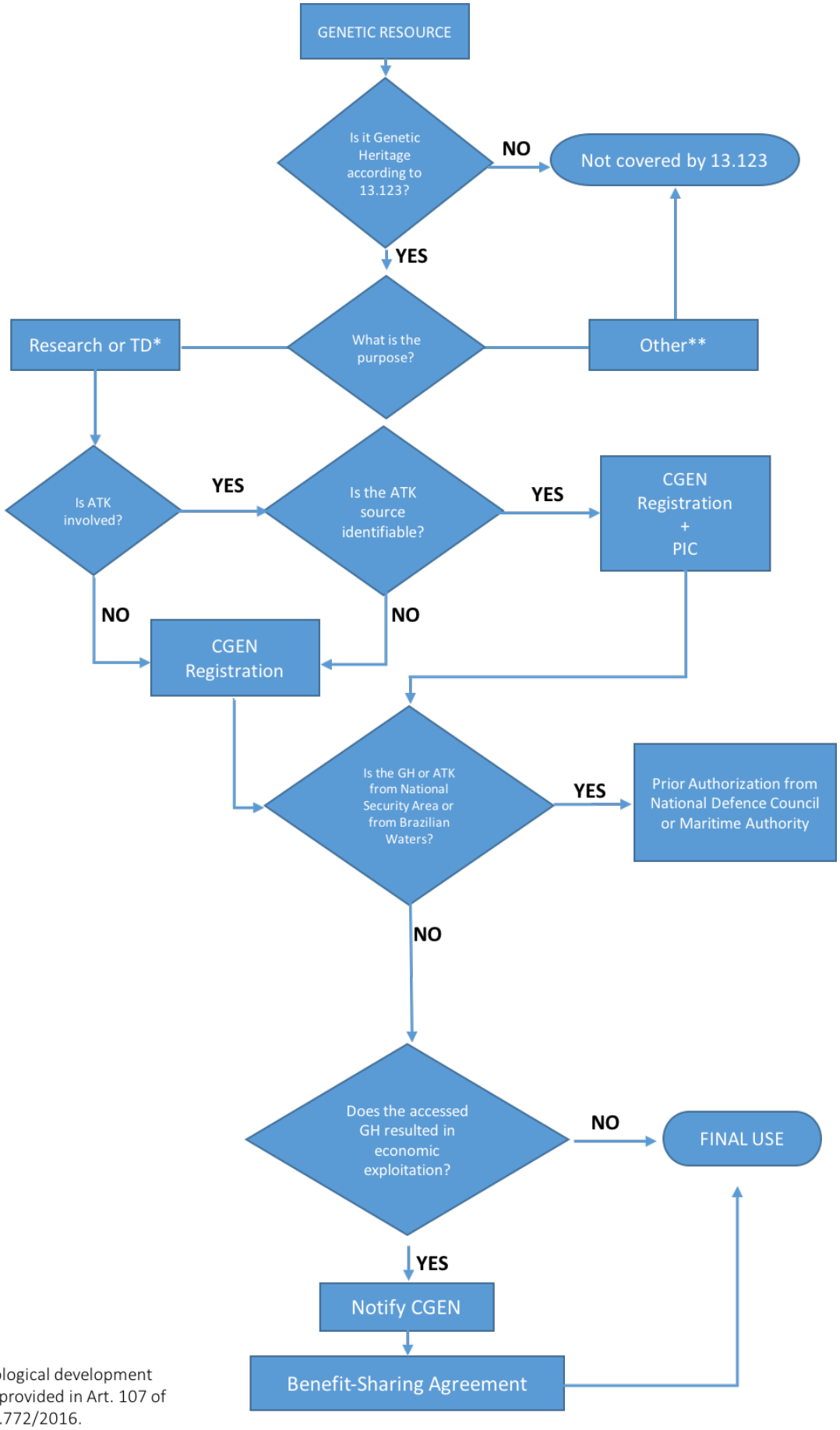
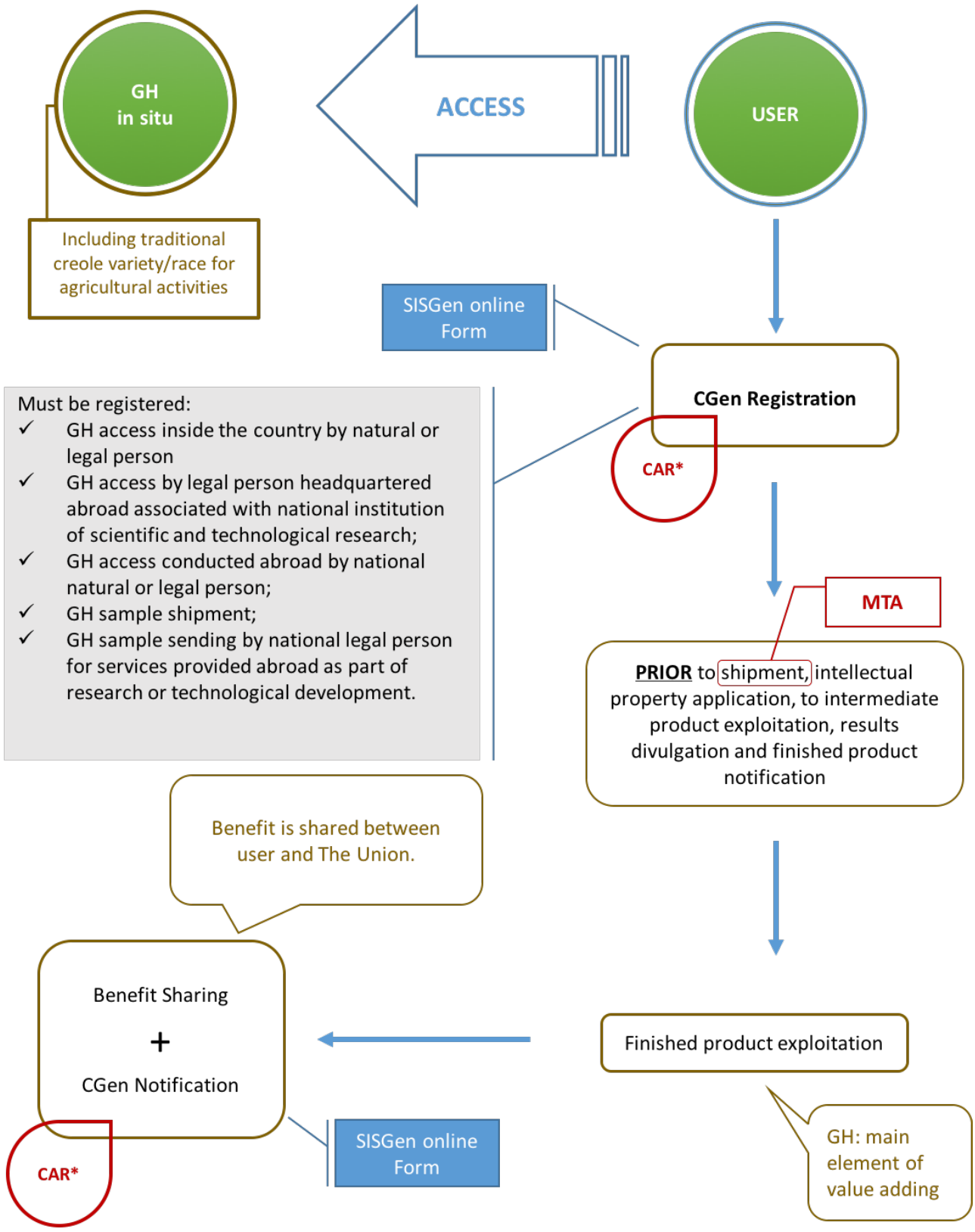


Figure 3 : Accessing GH/ATK according to the ABS Brazilian Legislation Law 13.123/2015.



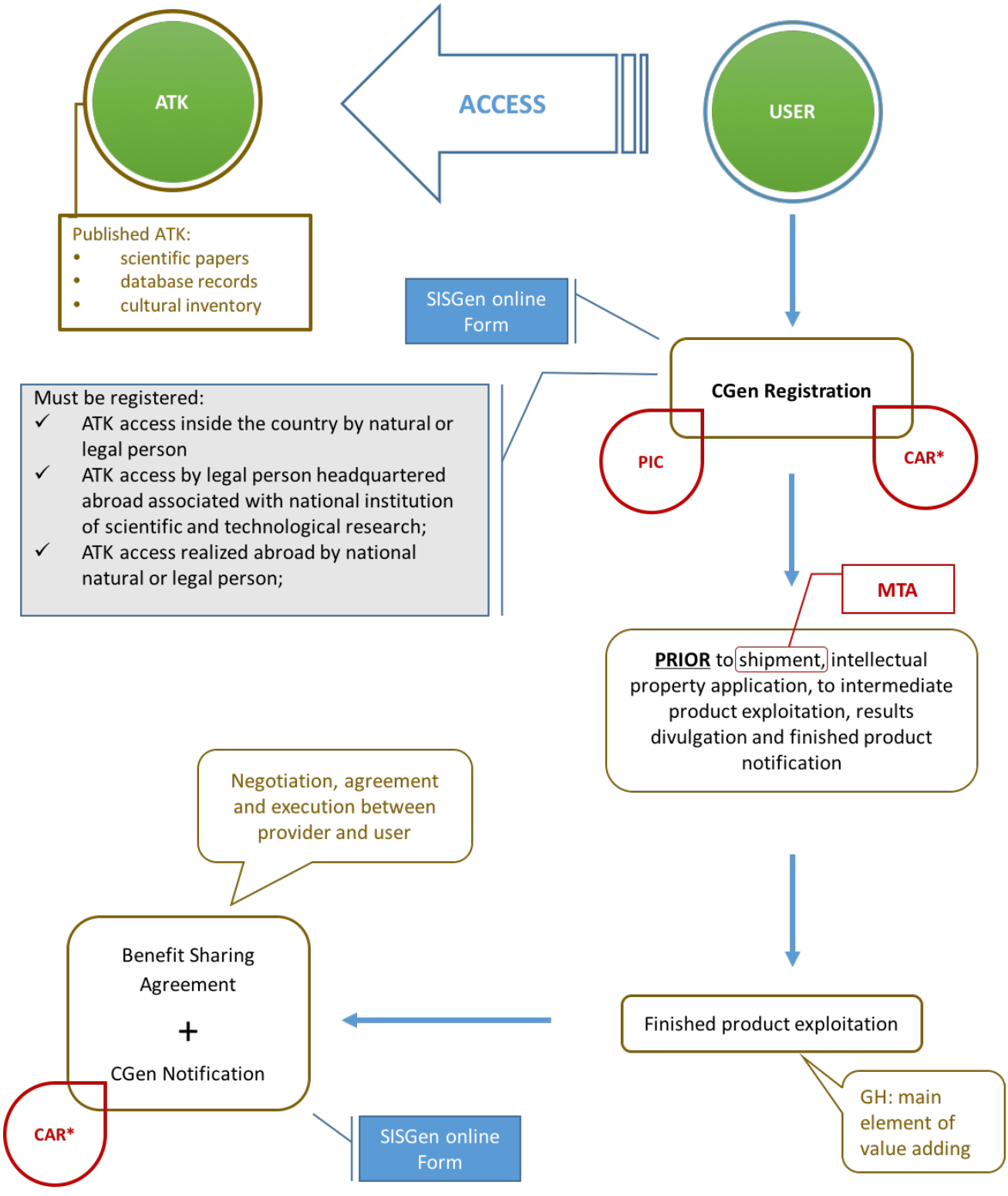
* TD: Technological development
** Activities provided in Art. 107 of Decree 8.772/2016.

Figure 4: GH Access without ATK according to Brazilian ABS Legislation



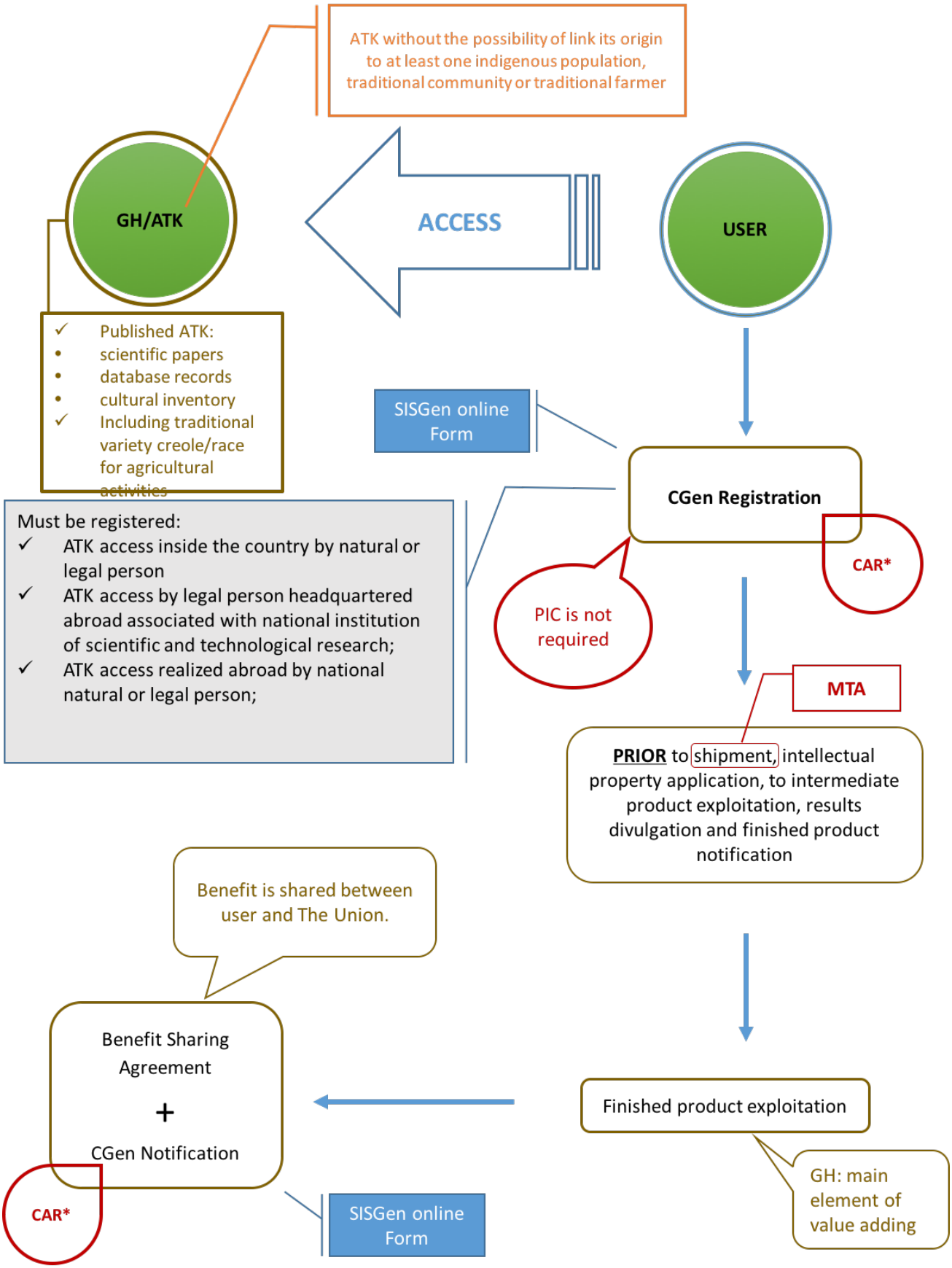
*CAR: Certificate of Access Regularity

Figure 5: Access to ATK with identifiable source according to Brazilian ABS Legislation.



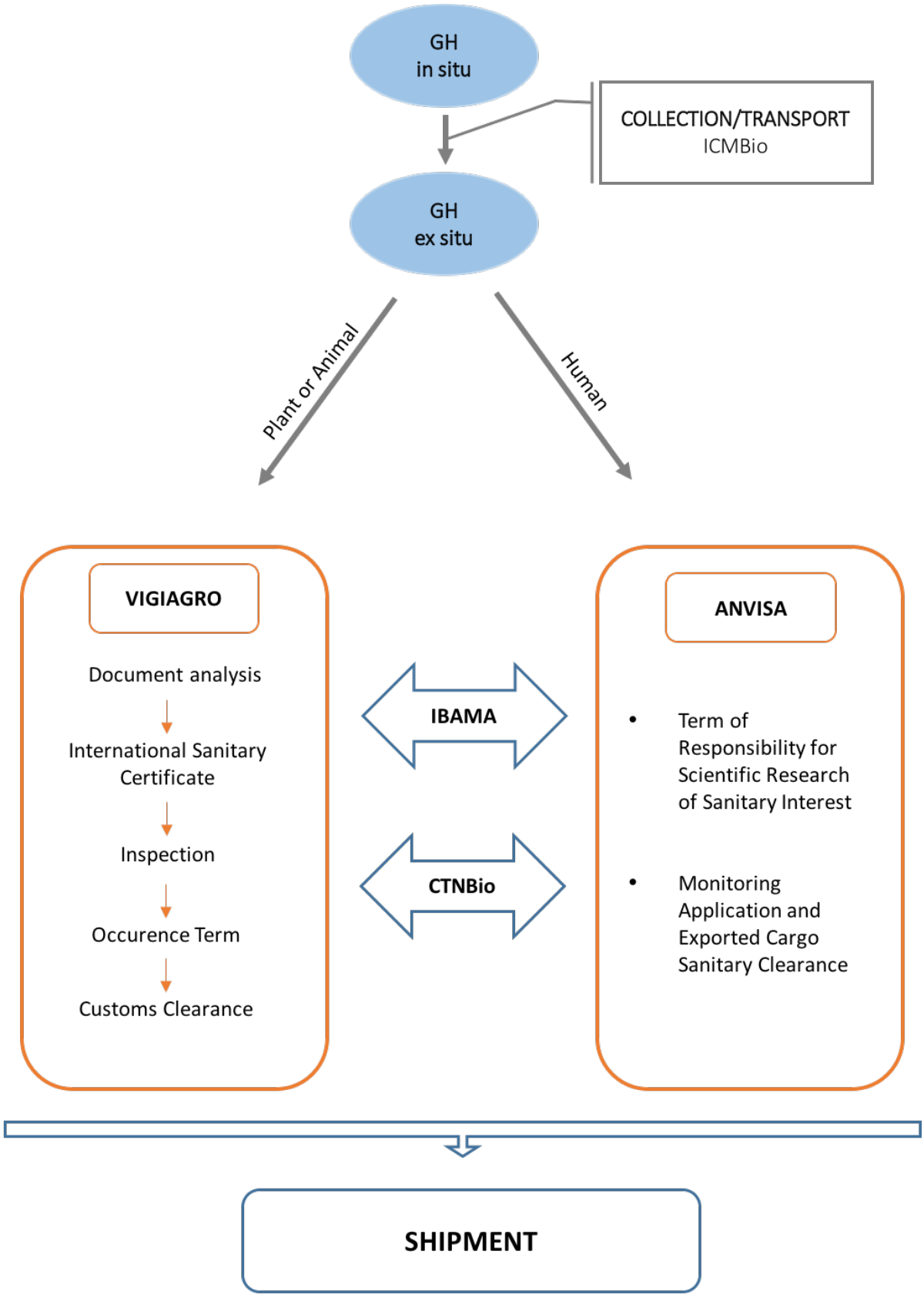
*CAR: Certificate of Access Regularity

Figure 6: Access to ATK with unidentifiable source according to Brazilian ABS Legislation.



*CAR: Certificate of Access Regularity

Figure 7: Collecting, transporting and shipping genetic resources from Brazil.



* When GH is associated with human derived material

Figure 8: Flow of genetic resources and ABS terms from *in situ* conditions via *ex situ* collections to utilisation by various sectors. (Adapted and updated post-NP from Fig. 1 in Tobin et al. 2005)

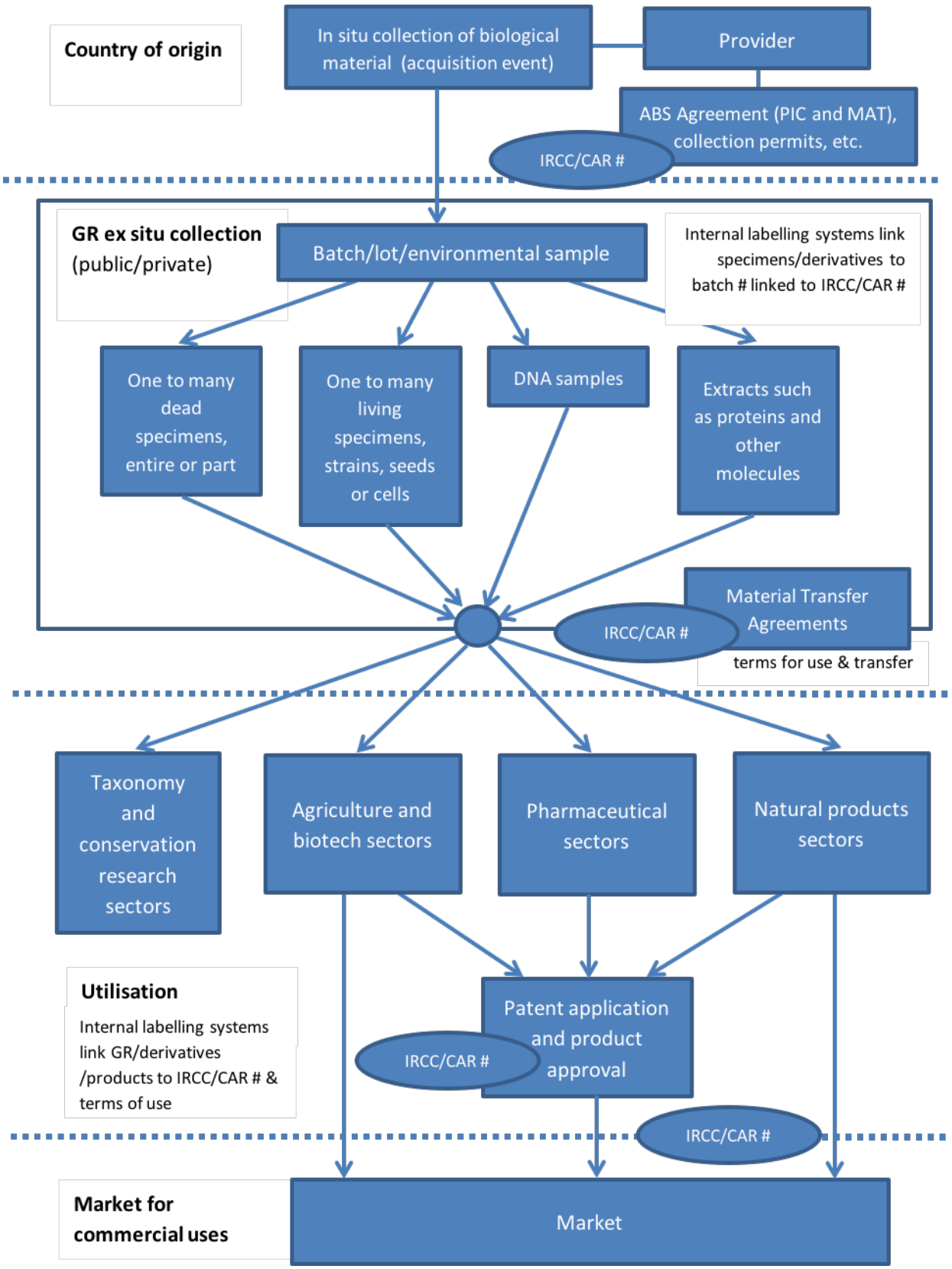
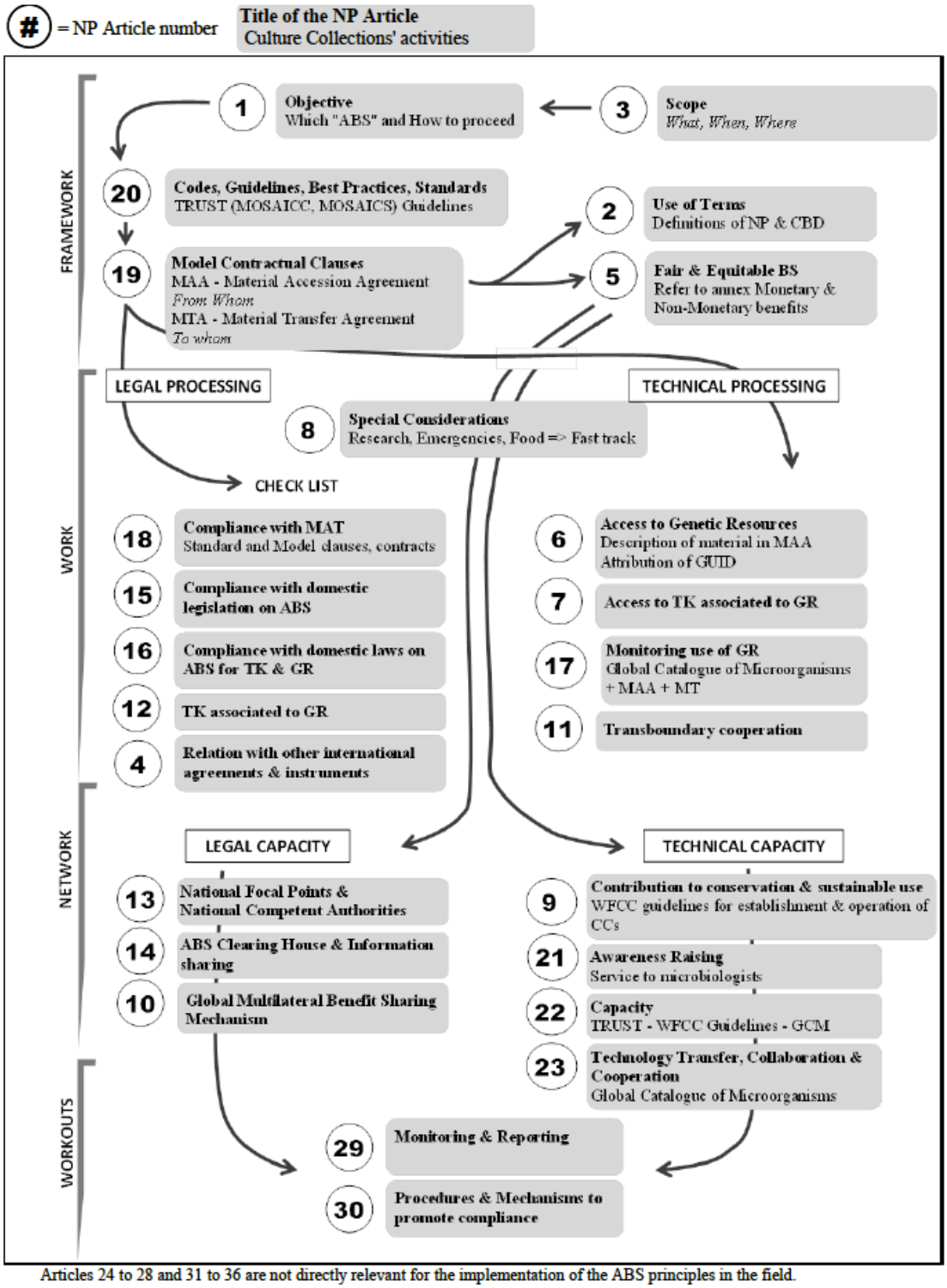


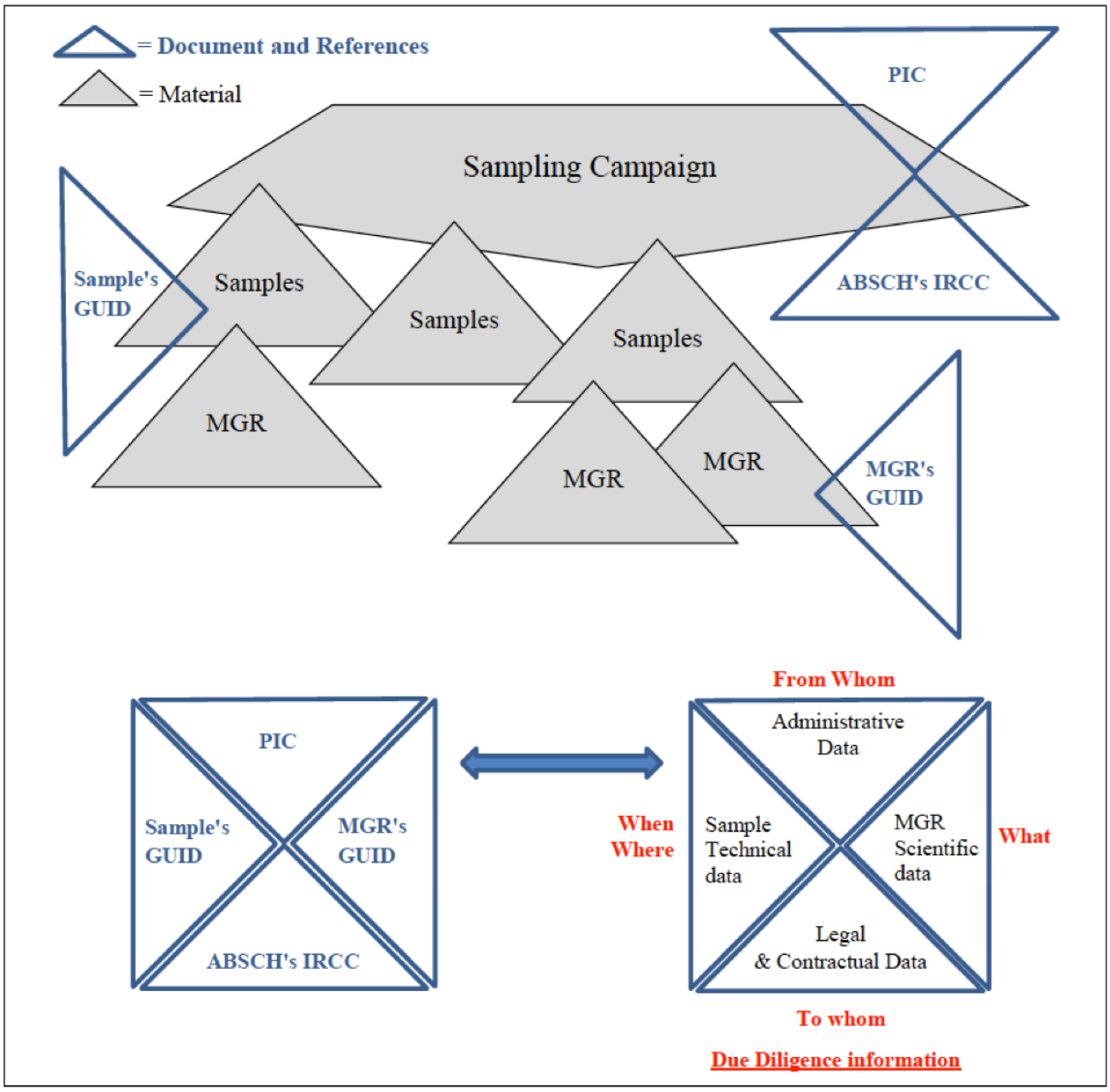
Figure 9: TRUST's structured reading of the Nagoya Protocol - Four works of the process.



Articles 24 to 28 and 31 to 36 are not directly relevant for the implementation of the ABS principles in the field.

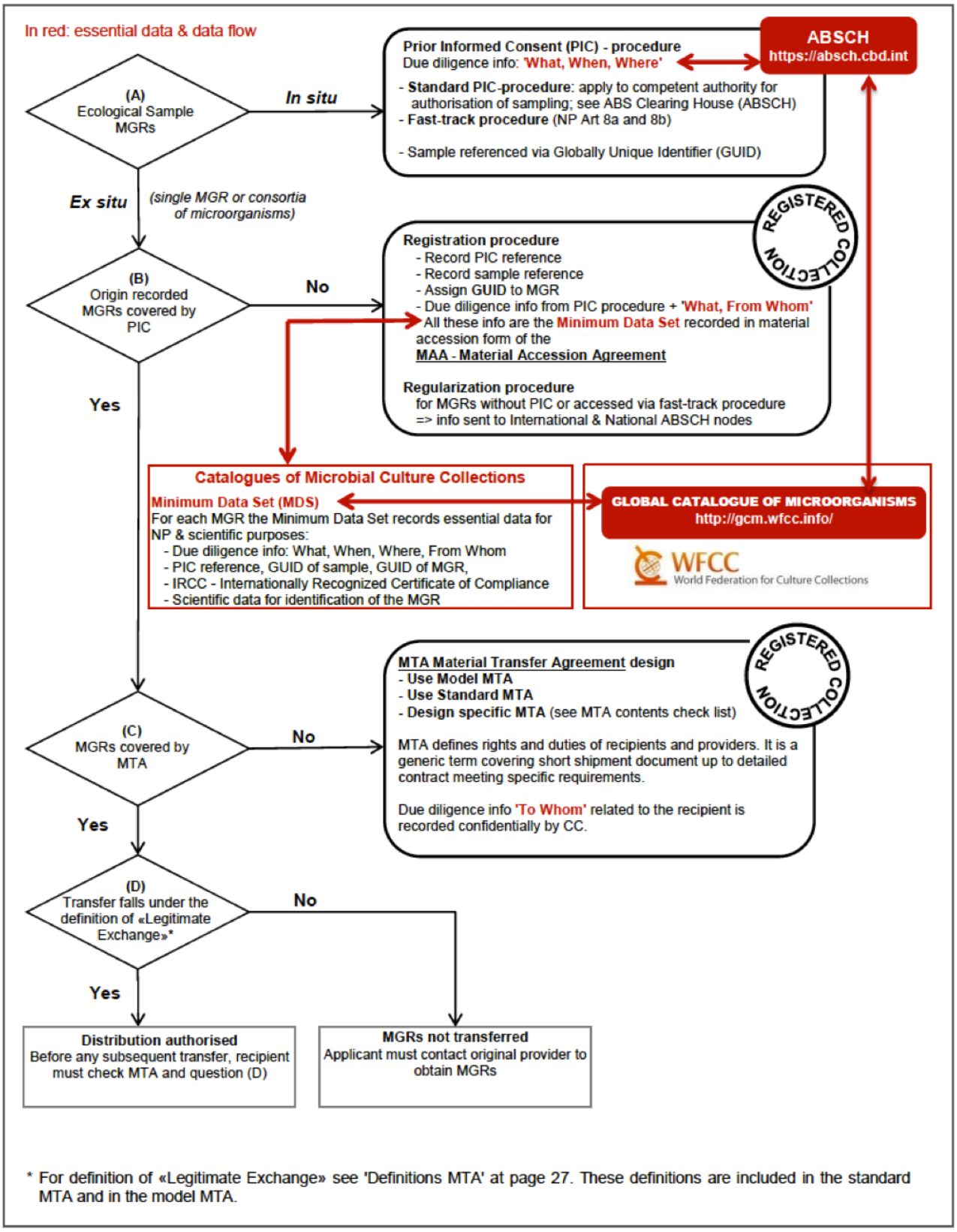
Source: TRUST March 2016

Figure 10: Trust approach for PIC, samples and GUID.



Source: TRUST March 2016

Figure 11: TRUST model - Procedure of access and transfer of mGRs.



Source: TRUST March 2016

Figure 12: Museum workflow, showing flow of GR and associated documentation.

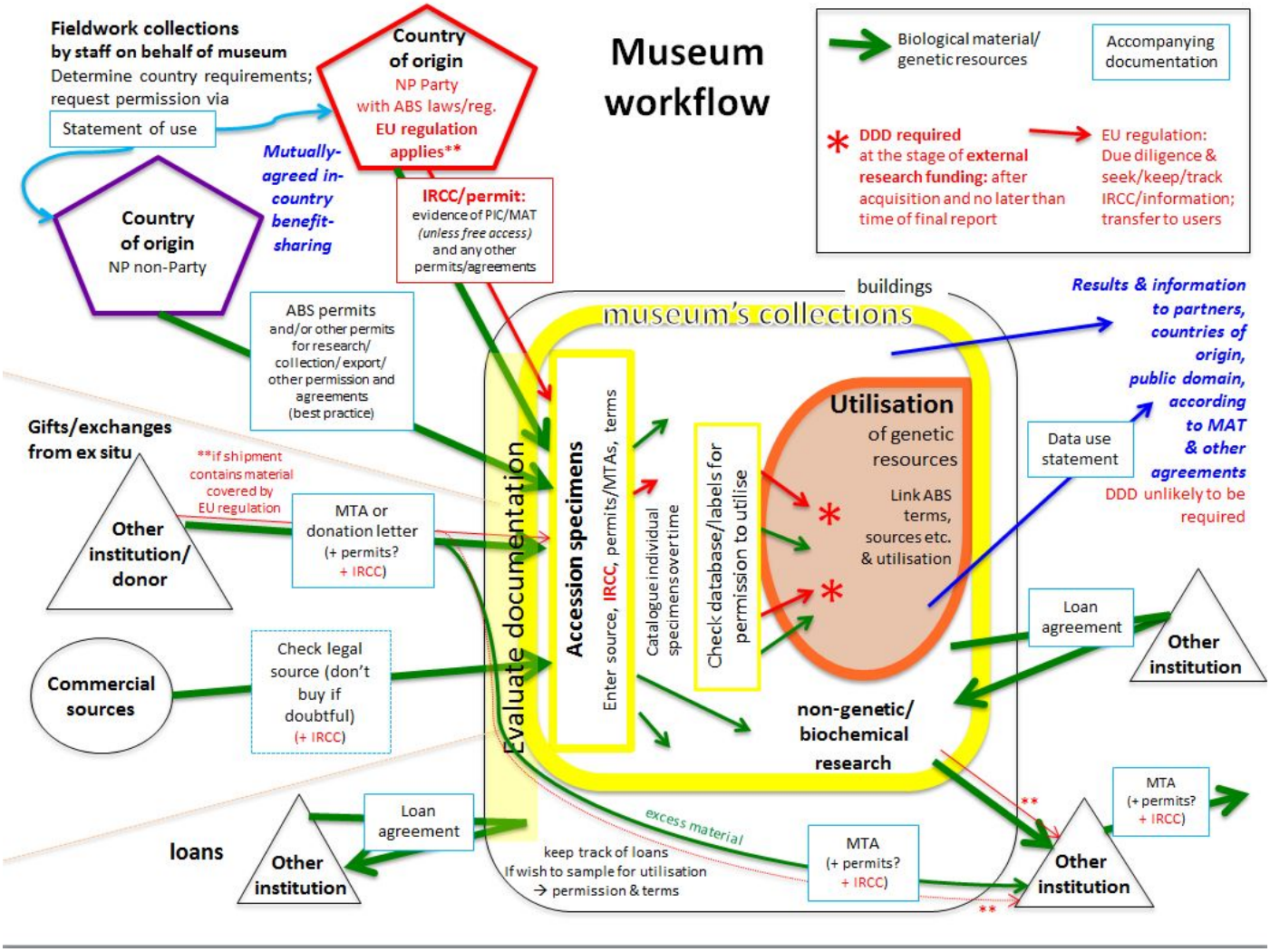


Figure 13: Life of specimen, showing range of forms and uses of a GR within a botanic garden.

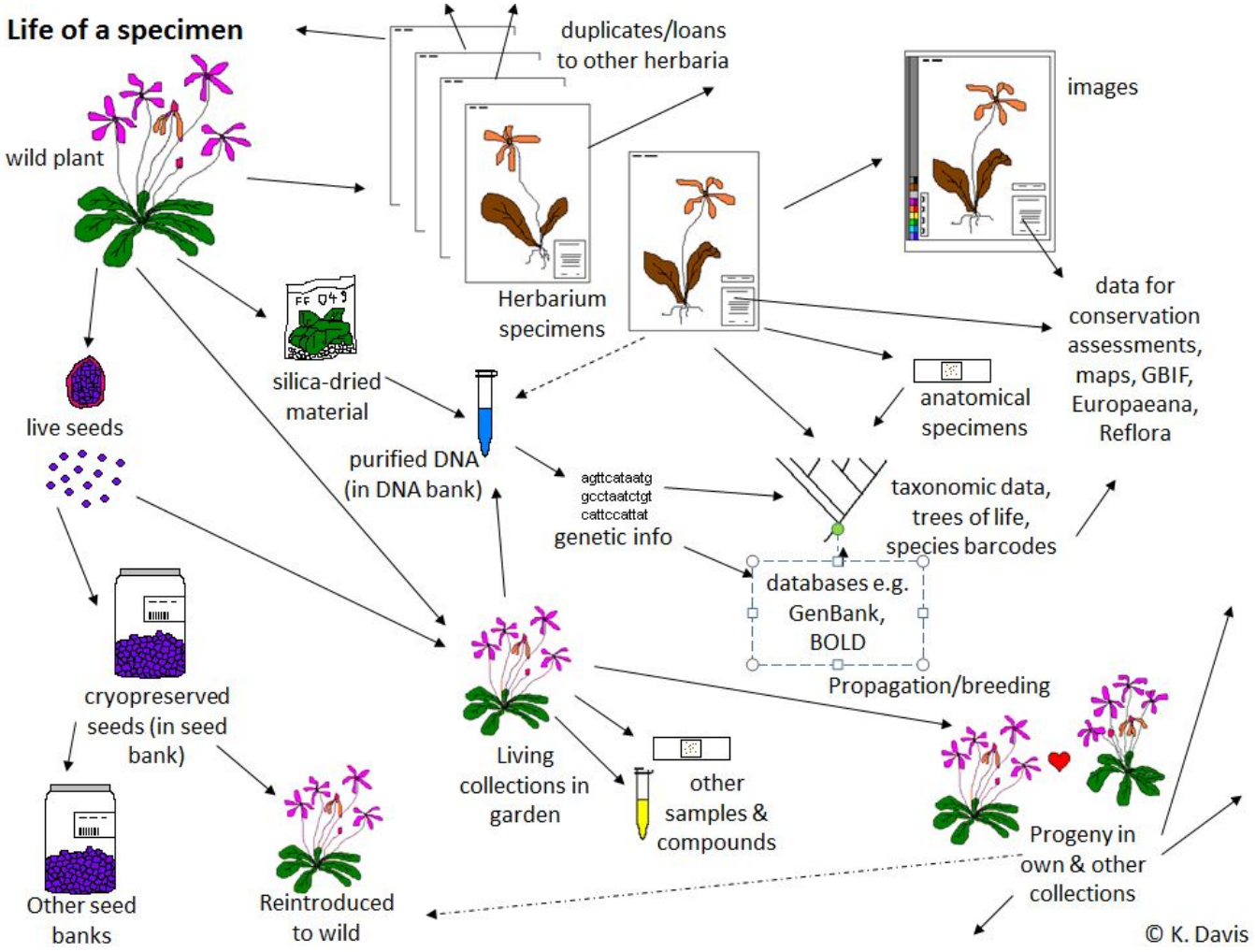


Figure 14: The plant breeding process. 'DUS tests' are tests for distinctness, utility and stability, required for plant variety under UPOV (the International Union for the Protection of New Varieties of Plants). Used with permission from Plantum.

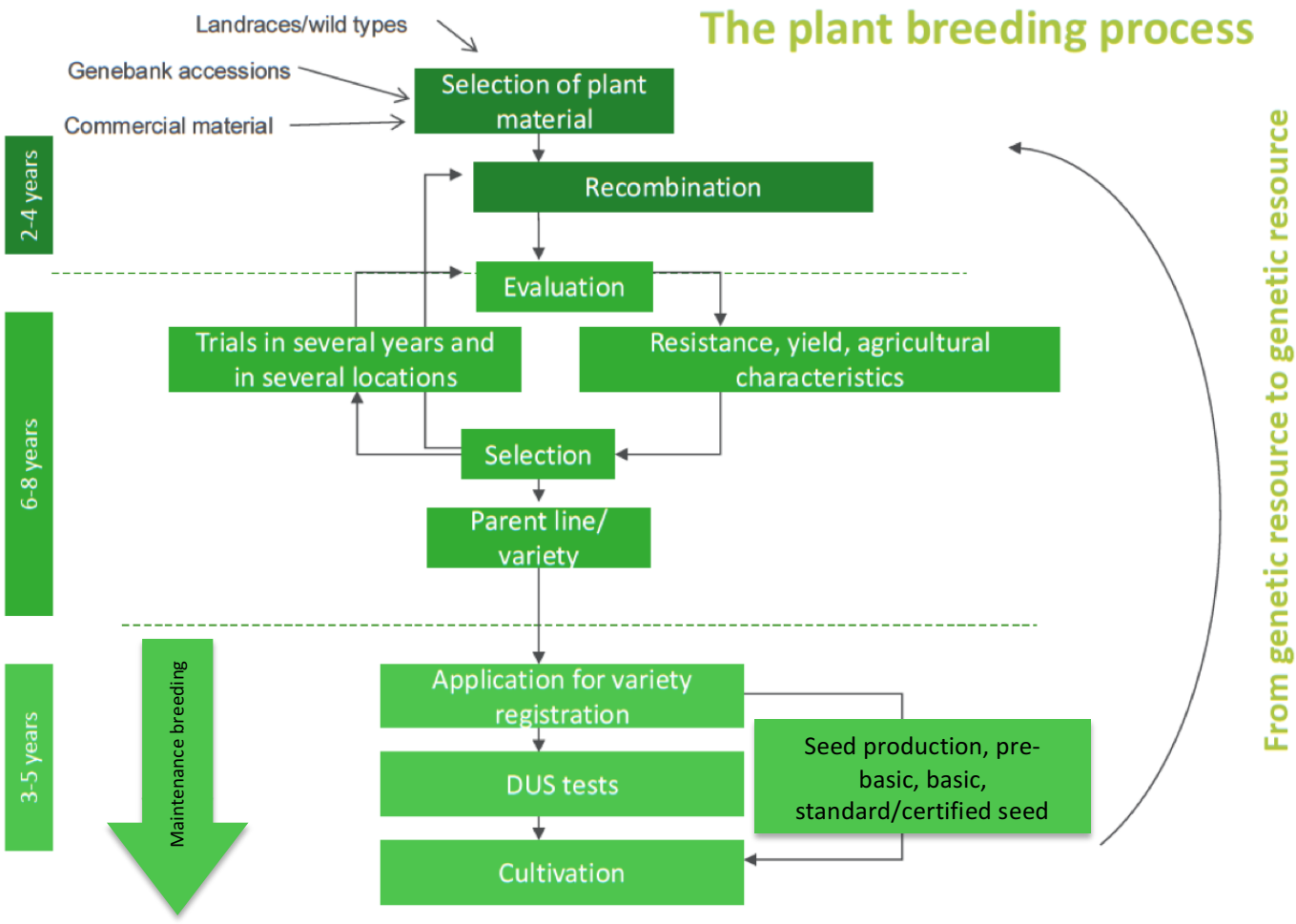
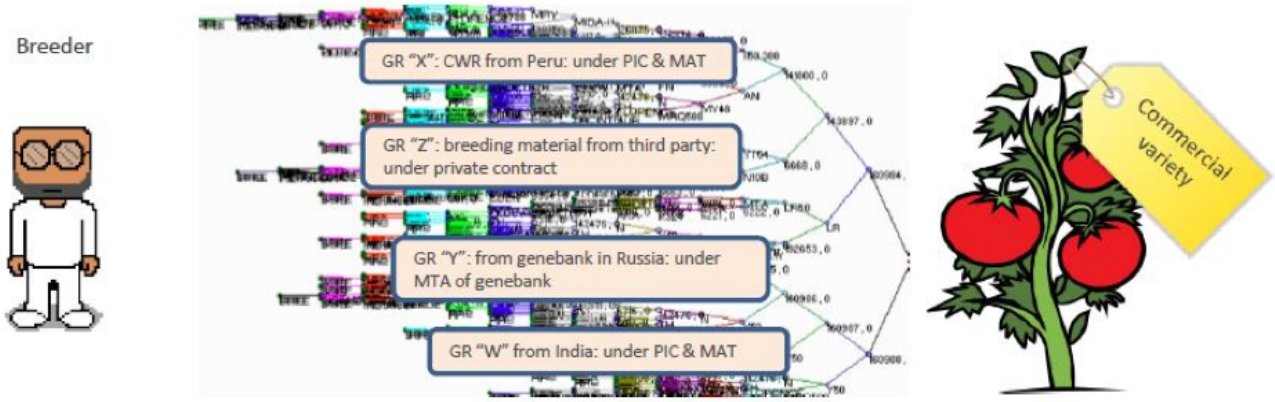


Figure 15: The impact of ABS terms on the seed industry, showing different terms that may need to be tracked during the development of new commercial variety. Used with permission from the International Seed Federation and the European Seed Association.



Annexes

Annex 1: Recommendations from 2014 analysis (Brazilian pharmaceutical industry study).

In another phase of the continuing EU-Brazil dialogue on ABS, Broggiato (2014)[97] conducted an analysis of the features and properties necessary for a monitoring, tracking and documentation system that is cost-efficient, effective and feasible, based upon a study of the Brazilian pharmaceutical industry. Her recommendations are summarised here.

Raising awareness and improving knowledge of sectors and best practices:

- Awareness-raising for all sectors that deal with genetic resources, via training in life sciences courses, ex situ collections and sectoral associations' meetings; costs of training should be met both by public funds and by stakeholders' internal funds.

- Requirements for ABS compliance imposed by public funding agencies for scientific research on genetic resources.

- Improved knowledge of different sectors' pipelines, exchange patterns of genetic resources within and across national boundaries, and between basic research, applied research and product development.

- Dialogue and relationship-building between sectors and government, and the encouragement and recognition by Government of sectoral codes of conduct and best practices, with incentives for their use (e.g. lighter administrative procedures), supported by awareness-raising regarding current codes and best practices and incorporation of elements of codes and best practices into monitoring and tracking systems.

- Selection of reliable sourcing partners for research and development, so that full ABS information is available for genetic resources and legal certainty can be assured for product development; Broggiato suggests this is likely to occur through a natural selection process.

- Integration of ABS tracking requirements into the industrial pipeline, with already existing legal requirements and best practices; in the case of the Brazilian pharmaceutical pipeline, Broggiato suggests a compulsory declaration by the suppliers of the source of resources and associated traditional knowledge, using the competences of ANVISA.

Scientifically based tracking: globally unique identifier

- If scientific analysis is done at the moment of access and registration and by a Brazilian public *ex situ* collection, CGEN could include the globally unique identifiers for the GR/samples in the PIC or permit [eventually the IRCC when Brazil becomes a Party]; or
- If the analysis is done by a user elsewhere and later in the process of research and development, CGEN could associate a wide series of unique identifiers with the access permit, to be associated with the scientifically-identified GR a posteriori.

- Because microbial collections are further advanced in their capacity to catalogue, identify and monitor the movement of GRs compared to other types, incentives should be created for all *ex situ* collections to publish their databases online, raising awareness of Brazilian microbial collections about capacity building opportunities provided by the Global Catalogue of Microorganisms, and encouraging other types of *ex situ* collections to develop their cataloguing capacity.

[97] Broggiato A. 2014. Final Report: Implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing – Third Phase. Projeto Apoio aos Diálogos Setorais União Europeia-Brasil.

Contractual tools for monitoring and tracking:

- Brazil should adopt 'standard mutually agreed terms' on terms of use and transfer to third parties and on monitoring and reporting duties on the users, as such contractual terms are the main legal option for monitoring and tracking. She suggests that the monitoring system does not need to focus on change of intent from non-commercial to commercial, because (monetary) benefit-sharing will be triggered by the final stage of the pipeline.

Reporting duties

- Regarding reporting duties, Broggiato suggests putting part of the costs and responsibilities of monitoring on users, and offers certain obligations for researchers to report:
  - results of the use of accessed GR/ATK and the eventual product developed – or at least, where confidentiality is an issue, notification to Cgen of the final product
  - every scientific publication produced from the use of the accessed GR/ATK
  - every transfer to third parties
  - users should be required to deposit a duplicate/voucher of each of the resources they use, into a national *ex situ* collection, to keep track of the GR accessed

  She does, however, point to the need for the receiving Brazilian institutions (CGen or other, and national *ex situ* collections) to have the capacity and funds to handle and interpret such information and maintain the material.

- Options are suggested for how reporting obligations can be triggered for users, in projects run by nationals and associated foreigners (accepting MAT by clicking at the point of registration in an online process, and/or by imposing reporting obligations via implementing acts) and in projects run by foreigners (a more complex authorisation procedure involving PIC as well as MAT, and 'clear and strict obligations for the users to report back to CGEN').

Third Party Transfer

- Transfer to third parties is considered to make tracking more difficult and costly; options suggested are:
  - To prohibit transfer (except with PIC), especially if it is to parties abroad or for commercial use;
  - to use the 'legitimate exchange' practice of the TRUST system, to cover transfer to third parties working on closely-related spin-off projects;
  - to use a viral license system [whereby the same conditions are accepted by and passed on by each user] to ensure that the provider country's conditions are imposed on subsequent users, as used by the MicroB3 project ABS model agreement, which would lower negotiation costs. The viral license model could be used when a user is an *ex situ* collection member of an international 'network of compliance' such as IPEN [though IPEN does not clearly address utilisation] or TRUST, and/or users working within publicly-funded scientific projects, within the project team, and/or for all transfer of GR between Brazilian users. It is suggested that for users abroad, viral licenses should be limited to non-commercial utilisation.

Material Transfer Agreement

- The use of a Material Transfer Agreement (MTA) for tracking is a crucial contractual tool; the report suggests that the standard MTA should include obligations to report to CGen.

Proposed system:

- The envisioned tracking system would contain three interoperable and interlinked databases - the registry, the authorisation database and the notification databases – and a scientifically based global unique identifier, and standard MTA imposing contractual obligations to report transfer to third parties[98]. Different burdens might be placed where there are commercial intentions (involvement of a private company or protection via intellectual property rights). The minimum ABS dataset supplied to the registry would be similar to that of the IRCC and the information needed for the EU regulation's declarations. A registry number could be associated with a GR or an R&D pipeline and subsequent users would only need the registry number, which might or might not provide previously stored information depending on confidentiality. When the GR is subsequently used by another user, one option for transferring terms might be a clickable online MTA and a declaration of the description of the research, user and any new GR, while another option would be a paper MTA.

  The registry should be accessible to or managed by checkpoints[99] and the interoperable and interlinked databases should be linked with the ABS-CH via the IRCC and the scientifically based global unique identifier.

[98] Unfortunately the report's Fig. 4 demonstrating the flow of information is not legible
[99] It is not clear which checkpoints are being referenced other than CGen.

Annex 2: Recommendations from 2013 workshop for Brazilian and EU collections.

Tracking and monitoring issues were considered by a group of Brazilian and EU representatives of *ex situ* collections and Brazilian policymakers at the 2013 workshop 'The role to be played by biological collections under the Nagoya Protocol'[100][101]. The recommendations that emerged from the discussions are set out below. Further explanation for the recommendations can be found in the text of the report.

Tracking and tracing

1: Develop a structured unique identifier (UID) standard as an efficient way to encode minimum set of standard data fields into a single UID that can travel with a sample and derived data, and reduce the need for other forms of documentation.

2: Standard lists of the codes for such structured UIDs should be developed and made accessible to all from a single place on the internet.

3: The creation of new UID systems in fields with already working systems should be avoided, but current UID systems should be examined, considering possible synergies.

4: The UID should travel with derived data (e.g. sequence data), and this requirement should be written into MTAs.

5: A core standard, with flexibility for different sectors, should be developed.

6: Unfunded mandates should be avoided. Requirements should be paired with implementation: the government that requires traceability should provide the required infrastructure (clearing house, regulating body) and funding to collections.

7: The degree of effort and resource expended on tracing should be proportional to the risk of mis-use.

8: A tracking system should be practical and scaleable to work for different collection holders, large and small, with different staff and infrastructure capacity.

9: There should be no requirement to assign UIDs retroactively to whole collections: UIDs should be used for new acquisitions and/or transactions.

10: MTAs should follow samples in a chain of distribution and should require reporting back to a clearing house.

Transfer to third parties and change of intent

11: A glossary of terms should be developed, to harmonise understanding of terms and concepts such as access, use and utilisation, trusted collections, third party transfer and MTA.

[100] Davis K, Marinoni L & Fontes E. 2013. Report on the Workshop 'the role to be played by biological collections under the Nagoya Protocol' as part of the Project under the 6th EU/Brasil Sectorial Dialogue Support Facility. Available at: http://www.sectordialogues.org/sites/default/files/acoes/documentos/relatorio_2a_oficina.pdf.

[101] Background document: Davis K, Fontes E & Marinoni L. 2013. Ex situ collections and the Nagoya Protocol:A briefing on the exchange of specimens between European and Brazilian ex situ collections, and the state of the art of relevant ABS practices. Available at*:* http://www.sectordialogues.org/sites/default/files/acoes/documentos/background_paper.pdf.

12: Information should be disseminated on the range of different practices for transfers, depending on the type of material.

13: The modalities should be considered for a system that could remove, but with safeguards, the requirement to gain Brazilian approval for third party transfer.

14: Each MTA should contain a glossary of terms (see Rec. 11), including a clear definition of 'third party' appropriate to the situation and sector.

15: Agreements (such as MTAs) should be made at the institutional level rather than at the individual level.

16: The Brazilian model procedure for benefit-sharing, which contains a useful approach for identifying change of intent, should be translated and the translations should be made publicly available.

17: The minimum requirements for a functional system to enable transfer to third parties that should be considered are:

- A series of standard functional MTAs for different circumstances containing
- appropriate information about terms of use;
- Benefit-sharing models in a range of languages;
- Legal and policy support and advice;
- Databases to record/provide information for purposes of tracking and tracing;
- Sufficient budget and staff resources: more standardisation lowers the costs.

The Brazilian MTA and alternatives

18: A single MTA with different possibilities invoking different clauses, linked to a decision tree, should be considered, to provide operational clarity and to ensure that appropriate legislation was followed. If it is not possible to have a single MTA, there should be a clear decision tree to determine which MTA is appropriate to use for particular situations.

19: There should be a means to clearly indicate relevant resolutions and discover text within resolutions, ideally in both Portuguese and the user language.

20: A web portal could be developed (on CGEN) as a tool to help institutions to develop the appropriate MTA, using such a single MTA model with options.

21: A list or register of Brazilian institutions that are empowered to sign MTAs should be prepared and made available.

22: The practicalities and requirements of a system to track delivery of non-commercial benefits (such as publications, as set out in MTA conditions) should be considered.

23: A data use agreement should be considered for publication of sequence data on GenBank/EMBL/DDBJ, and this recommendation should be considered across the EU countries.

Cooperation

24: Disseminate information that legislation and procedures in Brazil have changed and that Brazilian ABS legislation no longer impedes the exchange of material.

25: Import and export requirements for the exchange of material should be streamlined and simplified so as not to unnecessarily hamper exchange.

26: National authorities in Brazil should develop standardized forms and procedures to facilitate exchange of material.

27: A permanent online platform should be developed to provide and explain information on specimen exchange (ABS legislation and processes related to shipment and quarantine), using user-friendly, easy-to-understand simple schema and decision trees.

28: The needs of collections institutions in Brazil and in Europe that bear the costs of maintaining collections and providing services for basic research, conservation and commercial use should be recognised and supported.

29: The establishment of national nodes to deal with benefit-sharing should be considered.

30: Institutions should be encouraged to document and make their collections information available online to stimulate new collaborations and enable meta-analyses.

31: Collections should be encouraged to share information on ABS best practices with each other, between as well as within sectors.

Acronyms and abbreviations used

ABS	Access to Genetic Resources and Benefit-Sharing
ABS-CH	ABS Clearing House
ANAC	National Agency of Civil Aviation
ANTT	National Agency of Ground Transportation
ANVISA	National Agency for Health Surveillance
ATK	Traditional knowledge associated with genetic resources
BCCM	Belgian Coordinated Collections of Micro-organisms
BRC	Biological Resource Centres
CAR	Certificate of Access Regularity
CBD	Convention on Biological Diversity
CETAF	Consortium of European Taxonomic Facilities
CGen	Genetic Heritage Management Council
CITES	Convention on International Trade in Endangered Species of Fauna and Flora
CNA	Competent National Authority
CRB-Br	Brazilian BRC Network
CTNBio	National Technical Committee on Biosecurity
DDD	Due diligence declaration
ESA	European Seed Association
EU	European Union
FNRB	National Fund for Benefit-Sharing
GCM	Global Catalogue of Microorganisms
GGBN	Global Genome Biodiversity Network
GH	Genetic heritage
GR	Genetic resources
GR/ATK	Genetic resources and/or associated traditional knowledge
GUID	Globally Unique Identifier
IATA	International Air Transport Association
IBAMA	Brazilian Institute of Environment and Renewable Natural Resources
ICMBio	Chico Mendes Institute
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IPEN	International Plant Exchange Network
IRCC	Internationally Recognised Certificate of Compliance
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
LIMS	laboratory information management system

MAA	Material Acquisition Agreement
MAPA	Ministry of Agriculture
MAT	Mutually Agreed Terms
mBRC	microbial domain Biological Resource Centres
mGR	microbial genetic resource
MIRRI	Microbial Resource Research Infrastructure
MOSAICC	Micro-Organisms Sustainable use and Access regulation International Code of Conduct
MoU	Memorandum of Understanding
MTA	Material Transfer Agreements
NHM	Natural History Museum
NP	Nagoya Protocol
NPPO	National Plant Protection Organization
OECD	Organisation for Economic Co-operation and Development
PIC	Prior Informed Consent
REANSEM	National Register of Seeds and Seedlings
RNC	National Register of Cultivars
SBD	Seed Bank Database
SISGen	National System for Genetic Heritage and Associated Traditional Knowledge Management
SISVIG Supplies	Management Information System for the International Transit of Products and Agricultural
SVA	Services Agencies
TRUST	TRansparent User-friendly System of Transfer, for Science & Technology
UVAGRO	Agricultural Surveillance Units
VIGIAGRO	International Agricultural Surveillance System
WDCM	World Data Centre for Microorganisms
WFCC	World Federation of Culture Collections