WORKSHOP REPORT

MONITORING & COMPLIANCE UNDER THE NAGOYA PROTOCOL

MÉXICO GOBIERNO DE LA REPÚBLICA
SEMARNAT SECRETARÍA DE MEDIO AMBIENTE Y RECURSOS NATURALES
CONABIO COMISIÓN NACIONAL PARA EL CONOCIMIENTO Y USO DE LA BIODIVERSIDAD
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THE ABS CAPACITY DEVELOPMENT INITIATIVE
Convention on Biological Diversity

GOBERNANZA DE
LA BIODIVERSIDAD

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TECHNICAL WORKSHOP ON
MONITORING & COMPLIANCE
UNDER THE NAGOYA PROTOCOL

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DISCLAIMER

This report is based on various notes taken during the workshop. It does not intend to reproduce at length all debates and interventions. None of the messages conveyed in this report may in any way be interpreted as stating a national official position of neither the participants or that of the institutions partnering to organize and fund this workshop.

ACRONYMS

ABS	Access and Benefit Sharing
ABSCH	Access and Benefit Sharing Clearing-House
BfN	Bundesamt für Naturschutz (Federal Agency for Nature Conservation), Germany
CBD	Convention on Biological Diversity
CONABIO	Comisión Nacional para el Conocimiento y Uso de la Biodiversidad, Mexico
DEFRA	Department for Environment, Food & Rural Affairs, UK
GBIF	Global Biodiversity Information Facility
GGBN	Global Genome Biodiversity Network
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH (German Federal Enterprise for International Cooperation)
GR	Genetic resources
IGC	Intergovernmental Committee (WIPO)
IP	Intellectual Property
IRCC	Internationally recognized certificate of compliance (Nagoya Protocol)
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
M&C	Monitoring and compliance
NHM	Natural History Museum, UK
NP	Nagoya Protocol
NRS	National Recordal System (South Africa)
PIC	Prior Informed Consent
R&D	Research and Development
SCBD	Secretariat of the Convention on Biological Diversity
SEMARNAT	Secretaría de Medio Ambiente y Recursos Naturales, Mexico
SPDA	Sociedad Peruana de Derecho Ambiental
SWOT	Strengths / Weaknesses / Opportunities / Threats
TKaGR	Traditional knowledge associated to genetic resources
WIPO	World Intellectual Property Organization

BACKGROUND

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*, also known as the Nagoya Protocol, is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way, thereby contributing to the conservation and sustainable use of biodiversity. As countries advance in identifying the best avenues for implementation, the value of international technical exchanges and dialogues increases. On the one hand, these formats help countries to explore options for national ABS implementation, on the other hand they provide opportunities for (supra-) regional cooperation and harmonization of implementation mechanisms. One area of particular importance with regards to coordinated implementation is monitoring and compliance.

The Nagoya Protocol contains three basic provisions in relation to monitoring and compliance with the ABS requirements of provider countries:

i. to ensure that genetic resources utilized within a jurisdiction have been accessed in accordance with PIC[1] and that MAT[2] have been established, as required by the domestic ABS legislation or regulatory requirements of the providing Party (art. 15);
ii. to ensure that traditional knowledge associated with genetic resources (TKaGR) utilized within a jurisdiction has been accessed in accordance with PIC or approval and involvement of indigenous and local communities and that MAT have been established, as required by domestic ABS legislation or regulatory requirements of the Party where such indigenous and local communities are located (art. 16);
iii. to monitor and enhance transparency about the utilization of genetic resources, where designated checkpoints– at inter alia, any stage of research, development, innovation, pre-commercialization or commercialization – would collect or receive, as appropriate, information on (art. 17):
    a. PIC
    b. Source of the genetic resource
    c. MAT
    d. Utilization of genetic resources

This would also include keeping record and monitoring of permits and internationally recognized certificates of compliance where they are available. The ABS Clearing-House system plays a key role in this regard. More broadly, as part of an emerging *de facto* global system, the provisions of article 15, 16 and 17 of the Nagoya Protocol complement each other, and indeed, if designed and implemented in a coherent and efficient manner, can support the broader objectives of the article 15 of the CBD and the Nagoya Protocol as such. In this context, to create conditions to facilitate access for sustainable and sound use of genetic resources is key for promoting the conservation and sustainable use of biodiversity. Fully recognizing national sovereignty, coordinating national approaches to ensure that the emerging systems are effective and efficient will be one of the key challenges in national implementation.

The Technical Workshop on Monitoring & Compliance (TWMC) held on 3-4th November 2016 in Mexico City, provided a good opportunity to get a better understanding of the different approaches adopted by countries in implementing their compliance and monitoring obligations and to identify similarities and differences in order to provide the opportunity to coordinate and ensure coherence at the international level. The workshop was aimed at encouraging and supporting a technical dialogue among experts and countries that are developing and implementing polices and measures related to monitoring and compliance. It is anticipated that such dialogue will promote more effective and efficient measures, encourage cooperation and accelerate implementation.

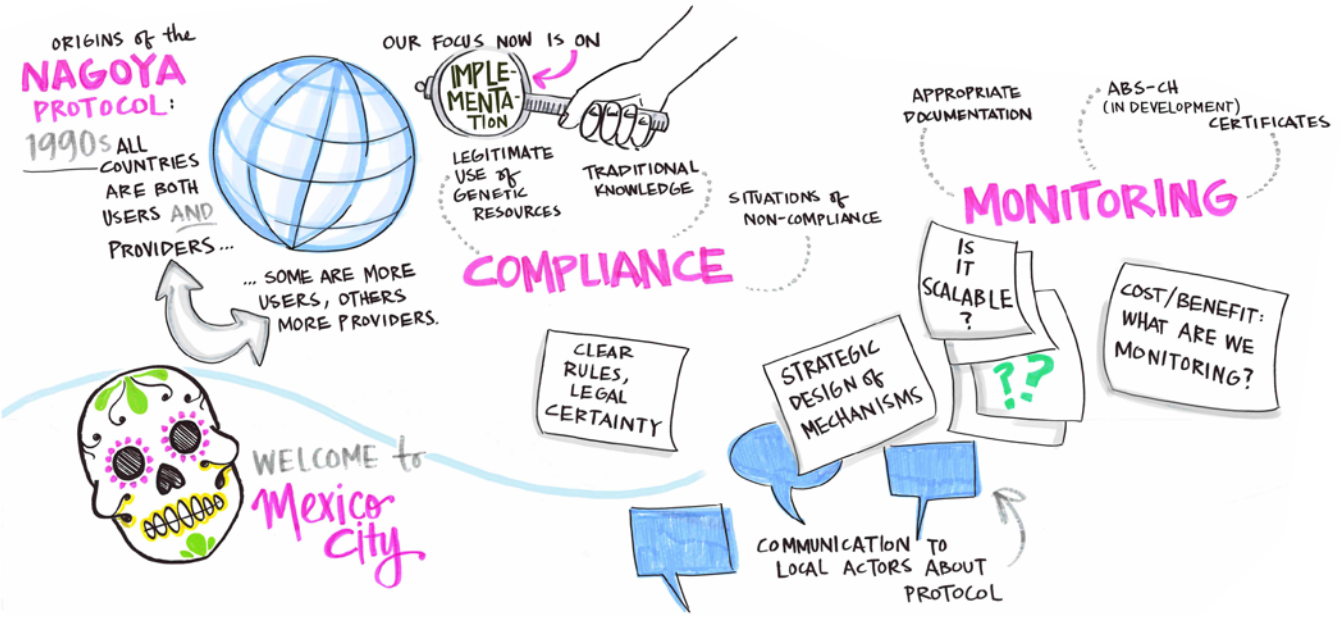
[1] Prior informed consent
[2] Mutually agreed terms.

OPENING AND WELCOMING REMARKS

The workshop opened with welcoming remarks by Pedro Álvarez Icaza (CONABIO), Valerie Normand (CBD Secretariat), Andreas Gettkant (GIZ) and Edda Fernández (SEMARNAT). Their remarks stressed the value of collaboration among countries and the sharing of experiences in order to advance into a more effective implementation of the Nagoya Protocol. They all shared their expectation that the workshop will provide a better understanding of the approaches being taken by Parties in relation with Monitoring and Compliance under the Nagoya Protocol.

Representatives from CONABIO and SEMARNAT stressed the great relevance of the workshop for the Mexican government, and particularly for the national process of implementation, led by an Intersecretarial Working Group on Genetic Resources presided by the Focal Point to the Nagoya Protocol.

SETTING THE STAGE



A discussion paper was prepared in advance of the workshop to provide additional context to participants with regards to Monitoring and Compliance under the Nagoya Protocol. Manuel Ruiz (SPDA), presented the paper. During the presentation, he outlined the concept of compliance as it is incorporated in Articles 15, 16 and 18 of the Nagoya Protocol, and monitoring, as it is incorporated in Article 17 of the Nagoya Protocol.

The presentation then concluded with a set of 6 considerations for the development of an integrated system:

1) A national ABS regime which is efficient and effective – in provider countries. If these are not in place there is no way USER obligations can become operational.

2) ABS regimes may be developed through a dedicated, exclusive law or regulation or through adjustments (e.g. inclusion of PIC, MAT, and benefit sharing provisions) to existing related legislation.

3) Management of information and coordination with other entities will be a key responsibility for national ABS authorities and for which capacities need to be developed.

4) The ABSCH is a key instrument to facilitate monitoring and contribute to decision making. Capacities to understand and use the ABSCH need to be developed.

5) R&D in genetic resources is becoming ever more sophisticated. R&D chains are complex. More and more, material vehicles (support) of "genetic information" are becoming less relevant – in certain research areas. This may have implications in regards to national ABS policies and regulations. There is a need to understand these realities to respond accordingly.

6) Actions of monitoring are long term, and may require long term commitments by national ABS authorities. This demands national capacities to undertake sustained monitoring along complex, dynamic, changing and varied R&D chains and transfers of materials.

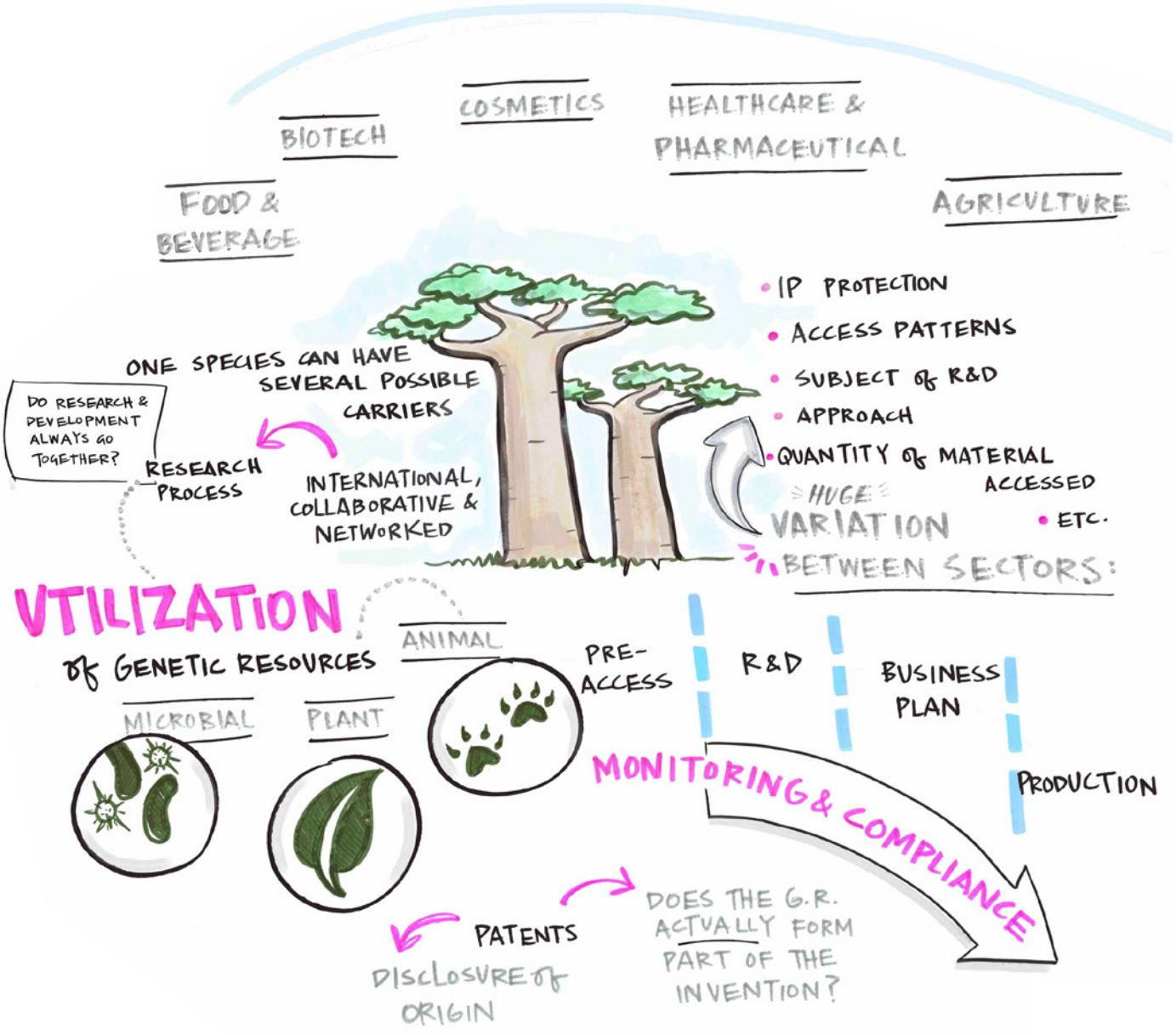
The paper triggered some initial discussion, during which there was some concern regarding the high expectations that countries as providers may have regarding the establishment of monitoring and compliance measures in countries as users of genetic resources. It was then noted that to a great extent, actions taken by countries as users will depend on the regulatory frameworks that are established in countries providing the genetic resource.

UTILIZATION OF GENETIC RESOURCES

Complementing the landscape of specific monitoring and compliance provisions under the Nagoya Protocol, this session on utilization of genetic resources sought to provide participants with an overview of the patterns of use, chains of utilization and sectoral user specificities. In order to develop a functional ABS system, it is important to consider all the relevant sectors and patterns of use. During the presentation, Suhel al-Janabi presented how the biotechnology, functional foods & beverage, pharmaceutics, cosmetics & fragrance sectors operate in an ABS context.

One of the most notable challenges in developing effective monitoring and compliance provisions is the diversity of access modalities, the broad range of purposes and sectoral spread. Another notable aspect of the patterns of utilization is their long temporality, given that the path from access to end utilization of

a genetic resource incorporated into a new product can even span decades. These raise a number of issues for countries as they advance in implementing their obligations under the NP regarding monitoring and compliance (see Table 1). In addition to these challenges it is also critical to have a sound understanding of the term "utilization of genetic resources"[3] (for instance, while new products can be derived from samples of organisms and/or associated traditional knowledge, these are not necessarily part of the new product itself, i.e. they may rely only on derived information).



[3] Article 2 of the Nagoya Protocol establishes that "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention on Biological Diversity. Adequately applying this term requires a sound and current technical understanding of the ways in which genetic resources are handled in biotechnology.

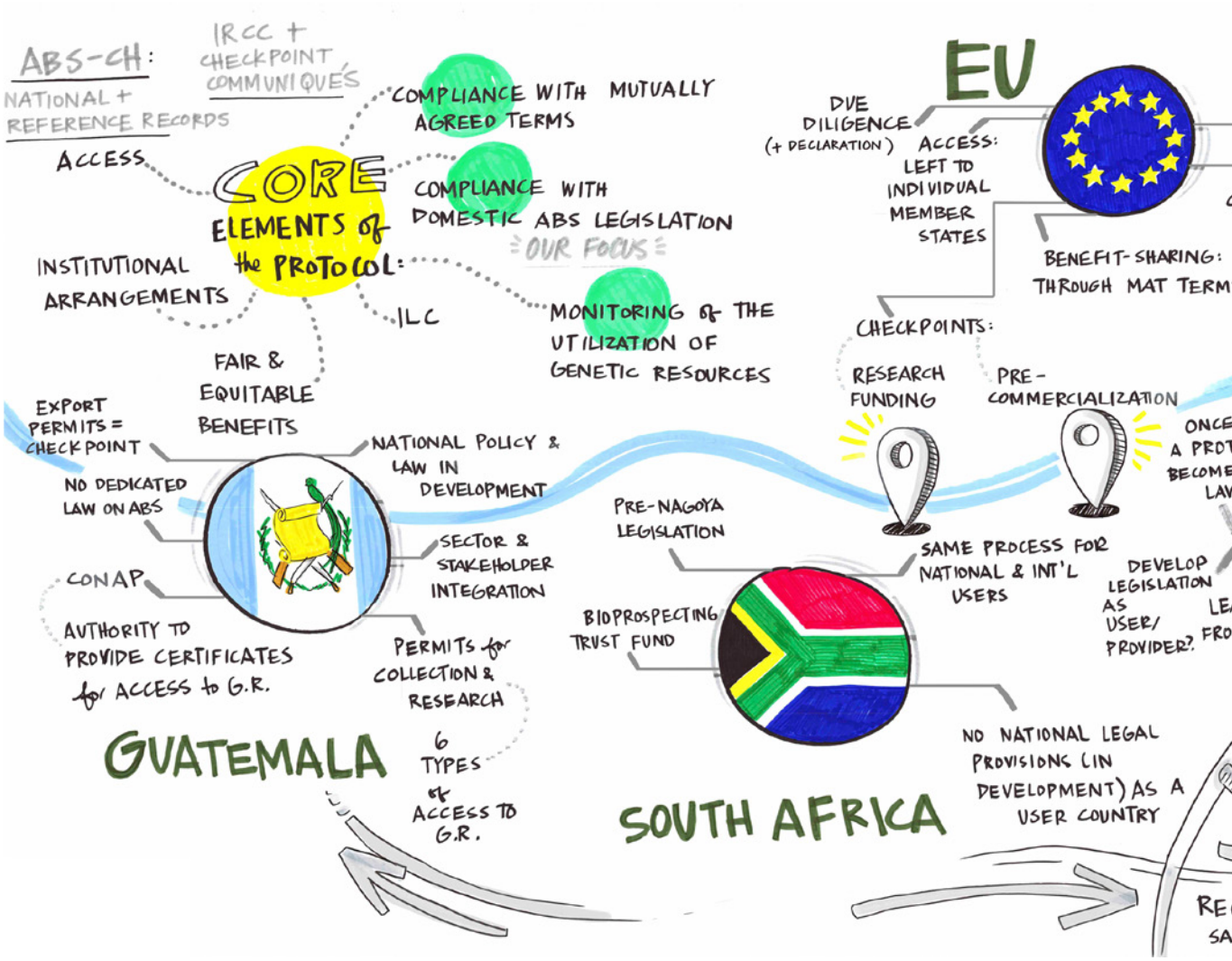
TABLE 1. Variation in patterns of utilization of genetic resources relevant for the design of Monitoring and Compliance measures under the Nagoya Protocol.

ISSUE	POSSIBLE PATTERNS TO CONSIDER
Access pattern	a) one off - periodical - continuous b) *In situ – ex situ*
Subject of R&D	Based on genetic resources – derivatives – biological resources (including commodites)
Quantity of material accessed for R&D	Immaterial (data[4]-) – tiny samples – several batches
R&D approach	Targeted / Random (high throughput)
Operational location of R&D	User does all in-house – Outsourced (partially / entirely). By public / private entities
Intellectual Property (protection)	Publication – patent – trade secret – none
Use of associated Traditional Knowledge	No – yes – used for reasons other than R&D
Existing Market Approval or other	Yes – no
Geographical location of R&D	Provider country – User country – shared R&D – Offshore R&D – Multiple countries
Jurisdictions	Provider NP Party? / User NP party where R&D is undertaken / Both parties? / NP party where marketing occurs?
Intent	Original no-commercial research changing intent to research with commercial purposes.

Considering the design of monitoring systems, it is clear that it is impossible to monitor everything, attempting to do so would likely result in great inefficiency. There is a need for countries to determine what the most relevant sector/chain is in a strategic way. For instance, given that the fair and equitable distribution of benefits is a central ultimate aim, the reliance of some of the user measures on the information found in applications for intellectual property protection does not resolve the problem entirely since most of IP applications do not lead to commercial or economic benefits. This was not to say that IP is not a relevant checkpoint, but rather that, while IP may generate some benefits, focusing too much on IP risks losing on many other benefits. As a result, addressing the broad range of possible patterns of utilization and the range of potential benefits should prompt a more substantive analysis of the M&C options for countries.

[4] This may include information on the genetic sequences of the genetic material per se, or information on derivatives or chemical structures.

ESTABLISHING COMPLIANCE MEA
APPROACHES AND EXPERIENCES



Keynote presentation by Valerie Normand on the Nagoya Protocol provisions related to compliance and the role of the ABS Clearing-House in supporting monitoring the utilization of GR

An overview of the Nagoya Protocol provisions on compliance and the role of the ABS Clearing-House (Article 14) in monitoring the utilization of genetic resources were presented. With respect to the ABS CH, an overview of its main functionalities was provided including a description of the three types of records it contains: national records, reference records and SCBD records (see https://absch.cbd.int/). In the case of national records, it was pointed out that each country must designate a "publishing authority" (which may be the ABS focal point) in order to publish national information, including information on competent national authorities, ABS legislative, administrative or policy measures and permits issued at the time of access.

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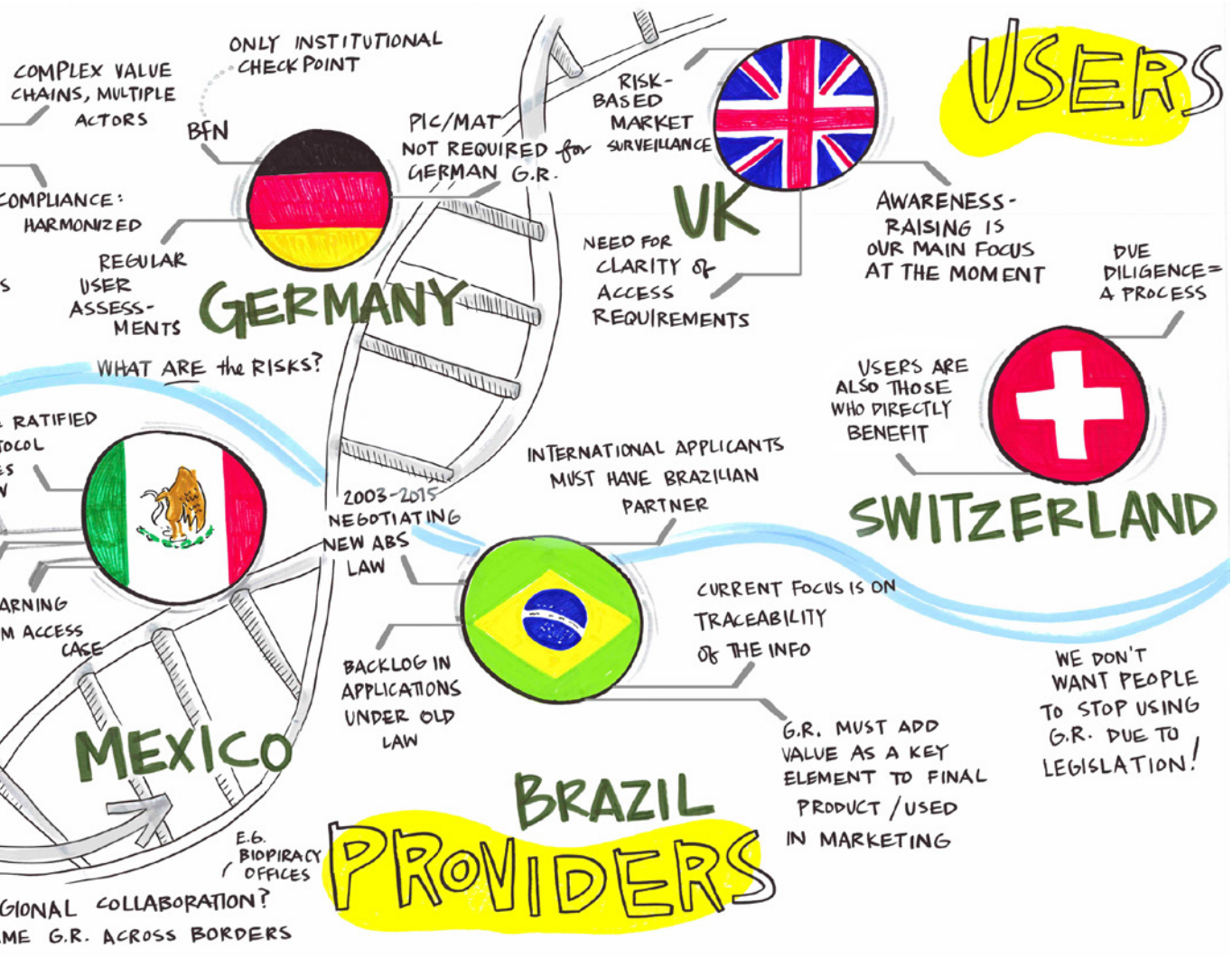


The monitoring system established under the ABS CH and its various components were also presented, including the role of internationally recognized certificates of compliance and check points in supporting monitoring and compliance. It was also highlighted that the SCBD provides technical support and has developed a series of awareness-raising and capacity-building tools to support Parties and relevant stakeholders in using and making relevant information available on the ABSCH. During discussions, participants focused mainly on clarifying the nature of the IRCC. Could an ABS contract stand as an IRCC? Are authorizations issued by provider countries an IRCC? There was discussion as to whether countries can issue an IRCC or are these only valid once incorporated into the ABSCH.

Country (regional) presentations on implementation of the Nagoya Protocol

A session was devoted at looking at how countries are implementing the Nagoya Protocol, in regards to compliance and monitoring in particular. The case was made that countries are always users and providers to varying degrees and that while the motivation from countries to implement the Nagoya protocol will vary according to the dominant role each country plays at a given time, there is a need for provider countries which are *also* user countries to establish compliance measures under Article 15-17 of the Protocol. This may not only allow for a better regulatory balance, but would also enable checking material coming from other jurisdictions.

An important element of the Nagoya Protocol is how it enables legal certainty for all actors. Check points may be one way to support legal certainty. For provider countries, typical check points are IP offices; but these may include many other instances such as research granting institutions or commercial permitting or sanitary authorities.

Very varied examples were provided from a broad range of countries. On the provider side, examples were provided for countries that have issued IRCC's (Guatemala, Mexico and South Africa), as well as from countries that have gone through various approaches to ABS regulations, like Brazil.

Guatemala explained how they had issued an IRCC without having a national regulatory framework on ABS. Considering the fact that this particular IRCC was based on genetic resources that are widely spread, some comments were aimed at how to deal with this given the geographical validity of the IRCC. In the case of South Africa, the benefit sharing agreement between a user and provider of genetic resources and/ or associated traditional knowledge is submitted to the Minister of Environmental Affairs for approval together with the issuing of a permit. South Africa established a formal monitoring system in the Patent Office for the utilisation of genetic resources and /or associated traditional knowledge through the amendment of the Patent legislation prior to the adoption and entry into force of the Nagoya Protocol. However, this check point has not yet been formally designated in terms of the Nagoya Protocol. In addition, South Africa has a established functioning Environmental Management Inspectors operating nationally who are deployed in all ports of entry and exit for compliance monitoring and enforcement on all environmental related regulated matters. In addition, sanctions and penalties have been established in cases of noncompliance with the ABS obligations. No checkpoints have been designated in terms of the Nagoya Protocol. A question still under consideration in South Africa is what exactly needs to be monitored as part of the user measures.

Mexico also presented an overview of their national process and the background to the issuing of their first IRCC. In updating its ABS provisions, Mexico stressed the need for a balance between measures of countries as providers and as users. Their first IRCC helped to highlight some of practical challenges, such as the fact that it was granted over a domesticated GR, where PIC and MAT had been obtained, but where the information was requested to be kept confidential. In addition, the user can enter into third party agreements to undertake R&D, but is bound to restrict the use of GR and derivatives to the provisions established in the MAT.

Brazil issued its new ABS framework in 2015. This replaces a previous legal framework that resulted in heavy costs of compliance and inhibited research. In contrast, the new framework takes a different approach, aiming to facilitate access and putting a greater emphasis on monitoring the final product. Benefits are only required once a commercial product is generated as a result of the value adding or R&D chain. To implement the system, Brazil has designated 4 check points: patent offices, the new plant variety protection office, the phytosanitary authority and research funding institutions. A key lesson from this experience is that by assuming itself as a user of GR rather than a provider, Brazil was able to rebalance its regulation, putting greater emphasis on capturing the benefits generated by products of biotechnology and reducing the emphasis on regulation at the point of access. These changes the strategic decisions regarding the design of monitoring and compliance provisions.

The European Union has developed comprehensive legislation (an EU[5] Regulation and an Implementing Regulation[6]) to enable implementation of the Nagoya Protocol. Whilst a few countries are developing "provider-type" ABS legislation (e.g. France, Spain, Croatia), the EU has developed a common framework, applicable to all member states, for compliance with the Protocol which focuses on the users. Measures to support legal certainty include check points (e.g. at the pre-commercialization stage

[5] Regulation (EU) No 511/2014 of 16 April 2014

[6] Commission Implementing Regulation (EU) 2015/1866

or as a prerequisite to access research funds), due diligence obligations and registration of ex situ collections (which have procedures in place to ensure legality of access). Additionally, best practices and guidance documents are also suggested as means to support compliance of the Nagoya Protocol. During the presentation, challenges and opportunities were identified. Implementing provisions on ABS involves developing a normative and regulatory environment for new applications developed through complex and often uncertain processes; in this context, the stifling effect of excessively complex ABS regulations could impact R&D and investment opportunities. Even the concept of "utilization" of genetic resources is not as clear as may be thought. Opportunities lie in the role of the ABSCH which, as a primary information sharing mechanisms, it can facilitate consistency across concepts and coordination across implementation mechanisms. At the same time, provider countries need to ensure their ABS frameworks are clear and enforceable. This is the only way in which the EU approach can be successful and effective over time. An important point raised during discussions was the limited attention placed on TKaGR although the Protocol and EU framework are applicable to it. Difficulties in addressing TKaGR include limited practice in negotiating MAT in regards to TKaGR, and the fact that only very few legal frameworks exist which specifically address TKaGR protection in provider countries. Users are even reluctant to utilize genetic resources which are associated to traditional knowledge, or to declare that they accessed it, given uncertainties regarding its legal status. This session also included presentations regarding the actual implementation of the EU framework in Germany and the United Kingdom, as well as in the Swiss legal framework.

Germany has adopted a law to complement the implementation of the Nagoya Protocol on the national level (Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014). Access to genetic resources in Germany is free and solely subject to the general restrictions of relevant national public and private law. Access to genetic resources in Germany is therefore not subject to PIC and MAT within the meaning of the CBD and the NP. The Federal Agency for Nature Conservation (BfN) acts as the competent national authority for ABS and is the main checkpoint; it is a one-stop shop for users of genetic resources. Good, up-dated and reliable, available information is the cornerstone for an effective compliance and monitoring system. The ABSCH and national ABS focal points (including BfN) have a critical role in this regard. Communication and collaboration among national authorities is also key. In the case of Germany, non-compliance may imply sanctions such as payment of penalties, disallowing access, etc.

The UK is a Party to the Nagoya Protocol. The UK Statutory Instrument puts in place the measures needed for the implementation of the EU Regulation at a national level. DEFRA is the National Focal Point and Regulatory Delivery (Department for Business, Energy and Industrial Strategy) is the Competent Authority, responsible for implementation and enforcement. As with Germany, the UK does not have access legislation and therefore users of UK genetic resources do not have obligations under The Nagoya Protocol. To date, Regulatory Delivery has focussed its activities on awareness raising to build and support understanding among UK users of genetic resources. Challenges lie in identifying all potential users of genetic resources and the route by which these resources enter the UK; ensuring that users understand the applicable compliance requirements; availability of clear access procedures of provider countries; and consistent regulatory approaches across EU Member States.

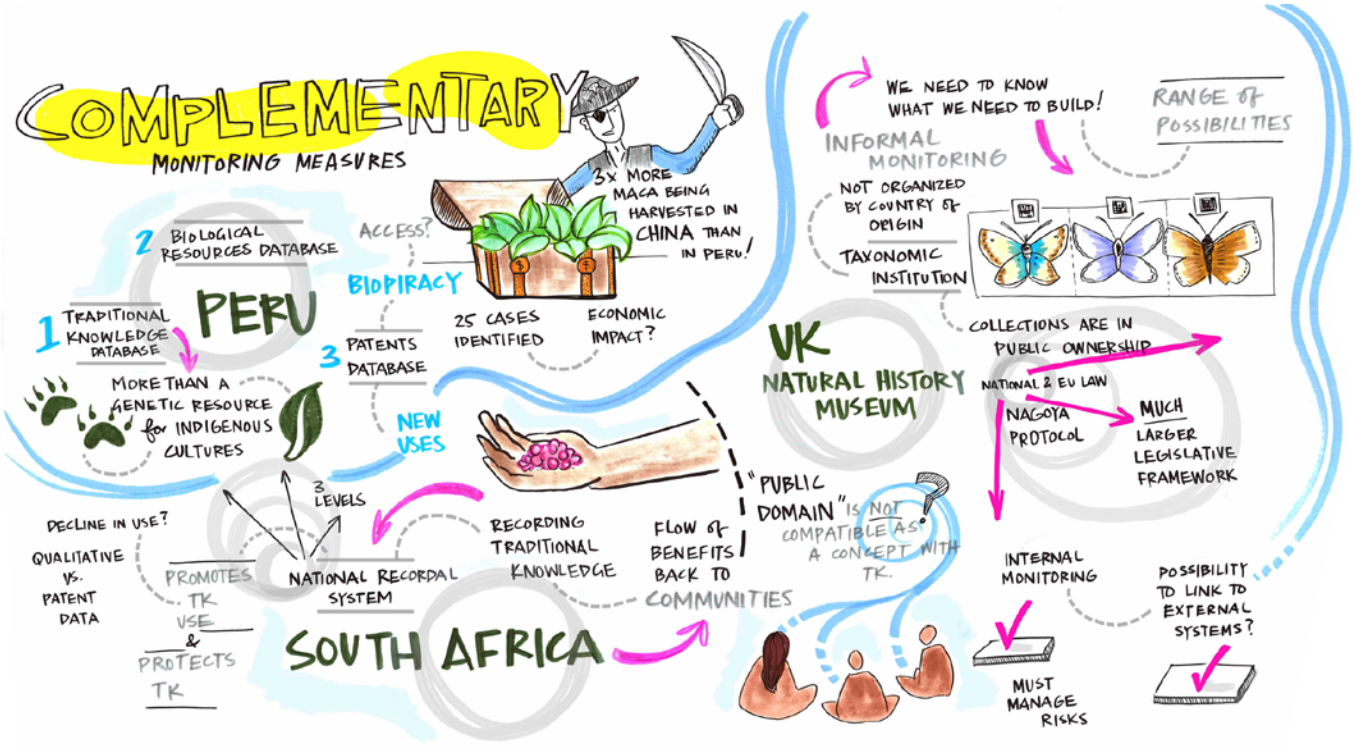
Finally, the session concluded with a presentation regarding the situation in Switzerland. To implement the new provisions of the Federal Act on the Protection of Nature and Cultural Heritage (NCHA) on genetic resources (including associated traditional knowledge), in force since 12 October 2014, a Nagoya related ordinance has been adopted and entered into force in 2016. Switzerland is now in the enforcement process. Switzerland has a due diligence requirement and a notification requirement to implement monitoring and compliance obligations under the Protocol. Interestingly, under the Swiss regulation users of genetic resources are not only those who carry out R&D but also those who directly benefit from the utilization of genetic resources. The country has also established a system of recognized best practices and collections. Other ordinances related to market authorization of products such as medicines have been modified to support compliance with the provisions of the Nagoya Ordinance (in particular the notification requirement).

The due diligence and notification requirements apply to genetic resources accessed after 12 October 2014, in a country party to the NP which has ABS measures in place. In the Swiss context, due diligence is seen as a *process* (not an event). Switzerland has over the years generated a series of tools for ABS including good practice guidelines, a toolbox for drafting MAT, notification forms in German and French, among others.

COUNTRY AND INSTITUTIONAL EXPERIENCES IN MONITORING THE UTILIZATION OF GR

An institutional approach to monitoring in Peru

A presentation was provided to share the experience in Peru in addressing monitoring in particular. Peru is a megadiverse and culturally diverse country. In 2004, a National Commission for the Prevention of Biopiracy was created by law. Biopiracy is legally defined. The Commission prioritized a group of plants for which there was evidence of widespread utilization in certain industrial sectors, such as foods, nutraceuticals, cosmetics and pharmaceuticals. Its focus is questionable patents granted over innovations based on Peruvian genetic resources and associated traditional knowledge. The Commission has developed a methodology to regularly follow and monitor patents applied for and granted worldwide. Mega-browsers and private tools allow this, although it is time and resource consuming. Over 25 cases of biopiracy regarding plants such as maca, yacon, sacha inchi and tara have been identified; most of these have been successfully and favorably resolved: patents have been either abandoned or reversed. The idea behind the Commission's work is not to eternally police but to demonstrate to the international community that biopiracy or misappropriation is a problem and international concerted actions and measures are required to reverse or address this phenomenon. The Commission has integrated a series of national databases on TK-aGR, genetic resources and international patent databases to allow monitoring and the possibility to alert patent offices about "problematic" applications or patents. An interesting question arose during discussions regarding the economic impact of the Commission's work: this has not been calculated although there is nonetheless a moral and social interest of the country and its communities which needs to be safeguarded.



Protection, Development, Management and Protection of Indigenous Knowledge Systems Associated with GR in South Africa

The National Recordal System (NRS) is an initiative of the South African Department of Science and Technology that supports communities, other TKaGR holders and practitioners in recording their traditional knowledge with the ultimate aim to create opportunities for benefits to flow back to the communities. These benefits may include community recognition, identity, sustainable livelihood, economic value and improved quality of life. It is constructed as an integrated system that expects to bring under one roof all the TKaGR assets in the country to benefit researchers and investment in indigenous knowledge systems. With a focus on unrecorded oral knowledge in the vernacular, the NRS is currently recording traditional knowledge associated with GR like Traditional Medicine, Food Security and Farming Practices. Its aim is not just to protect but also to promote the importance and use of TKaGR. To do that, it allows various levels of access and administers requests from users of various types (communities, patent offices, government, researchers, etc.). At present, the NRS has 56 communities and has received 1,159 claims of unauthorized use. Users can access the NRS if they comply with the law, i.e. they enter in partnership with a local community.

South Africa has developed legislation on traditional knowledge which is now in Parliament. The NRS website will be published once the bill is approved. While the issue of TKaGR which is diffused and publicly available is still under discussion at WIPO, South Africa's model is a significant example that can be shared more widely.

Monitoring the utilization of GR and TK in taxonomic collection and research, the case of the Natural History Museum

With 80 million specimens in the collection, and growing by the thousands every year, the challenges associated with data management for research and to comply with legal provisions are significant.

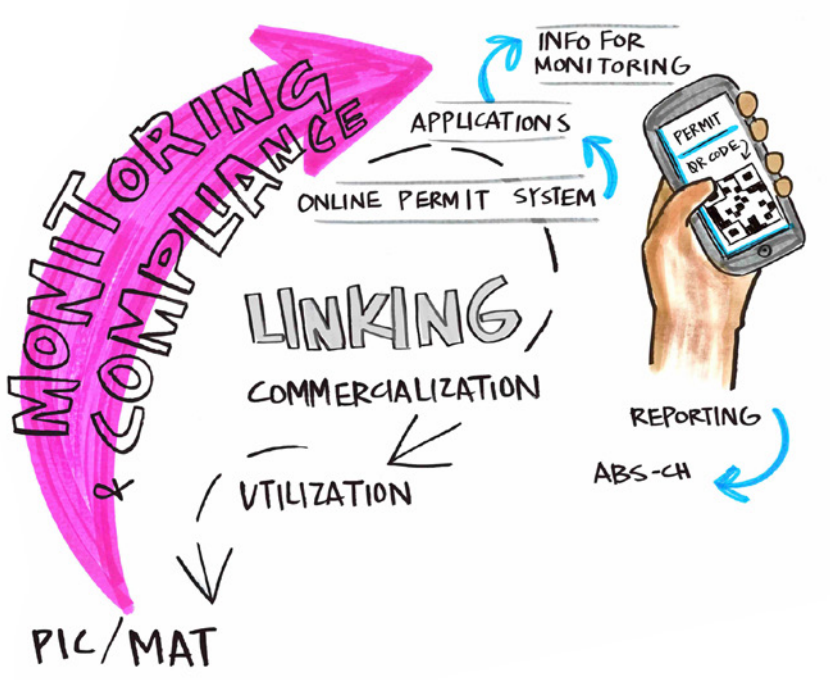
Taxonomic research is undertaken using a range of different tools and techniques (morphology, DNA sequences, genomics, biochemical analysis). The NHM is a non-commercial institution and its work is not aimed at commercial applications. Only a handful of projects are focused on TKaGR.

To comply with the already complex existing legal environment, institutions have developed also complex workflows to manage their activities. There are what might be called "ABS decision points" in a museum workflow – they are likely to require data recording for internal monitoring; these decisions points are not restricted to the Nagoya Protocol; neither are they restricted to material which will be 'utilized', in fact, the vast majority of the collection will never be used to access genetic information. To record these actions and manage collection activities, extensive databases are used at institutional level, sometimes at considerable cost. Recording information relevant to ABS compliance must be done in a cost-effective way to ensure internal monitoring and manage the risks of relevant actions being left out of the monitoring systems. The NHM uses a combination of tools to manage ABS compliance and facilitate internal monitoring (e.g. Codes of Conduct and Best Practices, MATs, use of materials statements, data use restriction paragraphs, GGBN extension to Darwin core). This supports reporting for external monitoring (e.g. through UK Checkpoint). 'Informal monitoring' by others is facilitated through increased publication of data and information (e.g. through GBIF, NHM Data Portal, scientific papers). Inclusion of IRCC or permit numbers would facilitate this. So far, academic journals do not require permit numbers, but there is potential to use them as part of a wider monitoring system. In particular, external databases could be connected to the ABS-CH.

Despite this effort, there are still challenges in the sector with regards to the implementation of the NP, such as the limited understanding of ABS regimes, emerging providing country legislation, complex contract management in light of non-standard clauses, and the cost of reporting. Further, requirements of monitoring and reporting under NP may not match existing data management. There are various possibilities to support informal monitoring, such as the agreement on protocols, introducing standards to journals and databases and supporting systems to access information.

LINKING MONITORING AND COMPLIANCE WITH PIC, MAT, UTILIZATION, COMMERCIALIZATION AND BENEFIT-SHARING

Linking Access, Compliance and Monitoring through an Online Permit System



One of the key challenges on compliance and monitoring is the capacity of governments to know what is happening with GR and associated traditional knowledge as they are used in multiple ways and for multiple uses. The proposal presented in this session relates to the development of a model online research permit and monitoring system. The basic key concept of the online system is to bring permits together into a single electronic permit system, facilitating monitoring efforts. The system allows governments to administer research permit applications involving genetic resources and associated traditional knowledge and to monitor compliance with the NP and prepare national reports.

Under the Online Permit System, authorities receive applications for access to GR that are then reviewed against a checklist and would either approve or reject them. All transactions would be electronic and would be recorded. Once approved, users must report any publications and patents. Each permit

would have a number and will be QR coded. In this way, information on publications and patents can be monitored and stored in new databases. This process would not only monitor use, but will also "capture" non-monetary benefits. The System takes into account the identifiers of the ABSCH and other databases. The ABSCH is part of the online model and information will be fed back into the ABSCH.

The model is currently being implemented in the Bahamas and Kenya through a GEF project. Given its open access strategy, the software code and tools for accessing literature and other databases will be freely available for other countries to use and adapt to their needs. It also aims to collaborate with collections (e.g. NHM, Kew Gardens) in trying out labeling to build trust and share the results.

DISCUSSION

During the discussion, it was noted that the ABSCH is useful for learning if PIC and MAT were obtained, but it does not allow providers to know if users are complying with the provisions of the MAT. If the ABSCH contained information on the conditions that users must comply with it would be easier to assess if users are complying with provisions or not. The relevance of MATs was further emphasized when considering that when dealing with non-Parties, MATs acquire greater relevance. In fact, MATs could include provisions related to disclosure or compliance with the NP.

Cost-efficiency was highlighted as a key aspect to take into account in any compliance and monitoring system that may not be fully taken into consideration as different entities adopt measures to implement the NP. For instance, providers like Peru and users/intermediaries like the NHM are both implementing tools and mechanisms to guarantee monitoring and compliance that seem to overlap and duplicate efforts rather than being synergistic.

Past accessions in collections, to the extent that they are sources of genetic material, could also undermine the effectiveness of the NP provisions if they do not comply with its provisions. In this regard, it is important to establish mechanisms to allow for the regularization of past accessions. This is particularly relevant since a number of collections are in countries that have ratified the NP.

KEY FINDINGS, RECOMMENDATIONS AND OPPORTUNITIES FOR COOPERATION

Key issues (presented by Pierre du Plessis)

The central role of Mutually Agreed Terms (MAT)

- MATs play a central role in making the system more effective. Although they are usually associated with a mechanism to ensure the distribution of benefits, they go beyond that role. They are also about information sharing, since there are significant non-monetary benefits that can be derived from the associated information.
- The value of some standardization in MAT was also raised as part of a regional cooperation. Standard provisions not just facilitate assessing compliance, but they could also facilitate sharing resources. There is also an additional value in terms of the capacity of standard clauses to develop a collective notion of "fair play", preventing the risk of countries "racing to the bottom" with users seeking the easiest country in terms of access.

Coordination at international level is key

- *Cost-effectiveness:* the tracking system needs to be simple and cost-effective (if it costs too much, it will generate no benefits). One database tracker would be efficient (for Africa, Asia, etc.)
- *Creating trust*: providers must be able to trust users that resources will be used legitimately

Seizing the potential of information technologies

- The interconnectedness of systems is a source of vulnerability but could also offer opportunities. For instance, can we work towards an automated system to resolve some legal aspects?
- An online system can encourage standards, including for non-commercial research, etc.

Measures to date are valuable

- Disclosure requirements in patent applications are helpful and are a relevant building block of the monitoring and compliance architecture.

Value of standardization

- Different definitions, particularly regarding access, R&D, utilization, are still challenging for monitoring and run the risk of limiting the capacity of promoting compliance.

Important role of the ABSCH

- The ABSCH is a key tool for facilitating the implementation of the NP, particularly for monitoring the utilization of GR along the value chain, but has its limitations when it comes to the content of MAT and possible standards.

Additional comments

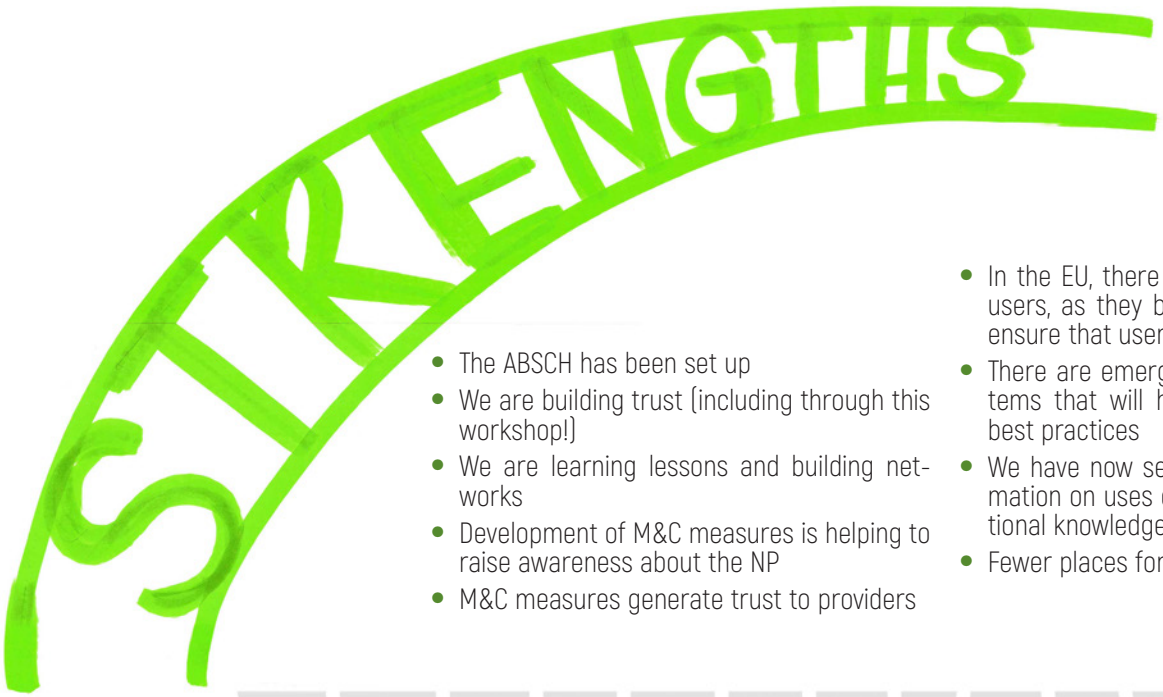
In the open discussion, additional issues were raised, including:

- Many countries/institutions are working on different types of systems to optimize processes, but there is a risk of redundancy and lower effectiveness.
- Non-Parties to the NP are still a challenge, limiting the effectiveness of compliance measures and MAT with a non-Party pose challenges in tracking.

Legal certainty can only be achieved through PIC and MAT. For them to be effective, information flow is a crucial part of the system.

Rapid SWOT analysis of the current implementation status of monitoring and compliance measures.

During the last part of the workshop, group' discussions were organized to address the Strengths-Weaknesses-Opportunities-Threats for the development of effective Monitoring and Compliance systems. The result of the exercise is presented below:

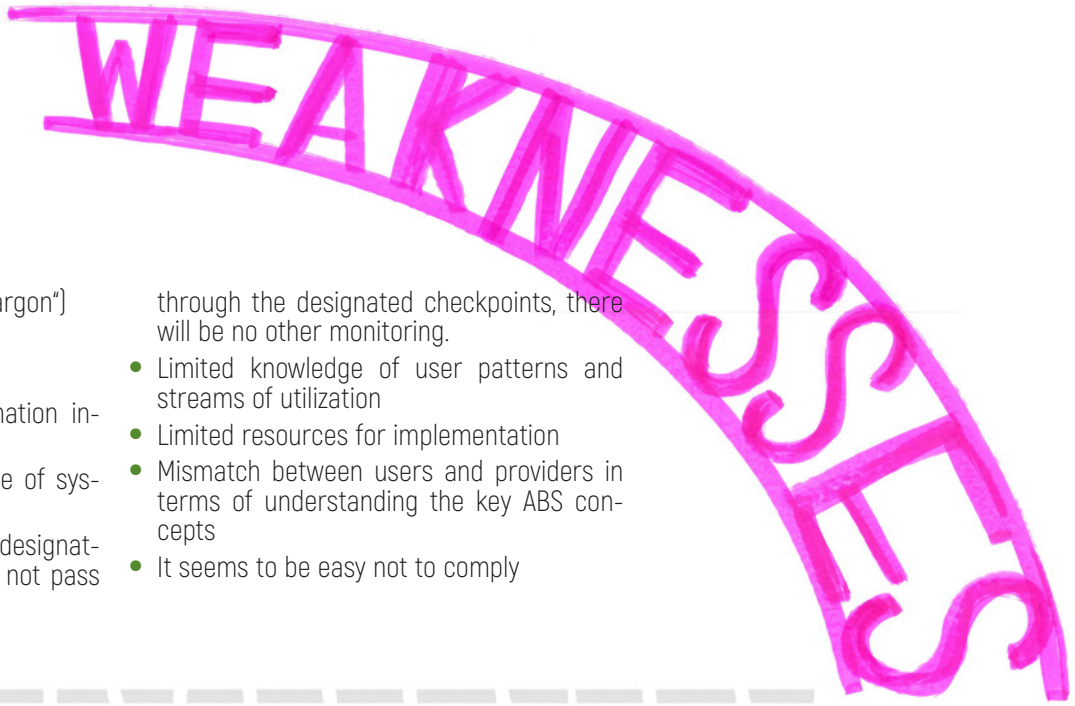


- The ABSCH has been set up
- We are building trust (including through this workshop!)
- We are learning lessons and building networks
- Development of M&C measures is helping to raise awareness about the NP
- M&C measures generate trust to providers
- In the EU, there is a lot of action amongst users, as they begin to set up systems to ensure that users will comply
- There are emerging examples of M&C systems that will help generate lessons and best practices
- We have now searchable sources of information on uses of GR and associated traditional knowledge
- Fewer places for biopirates to hide

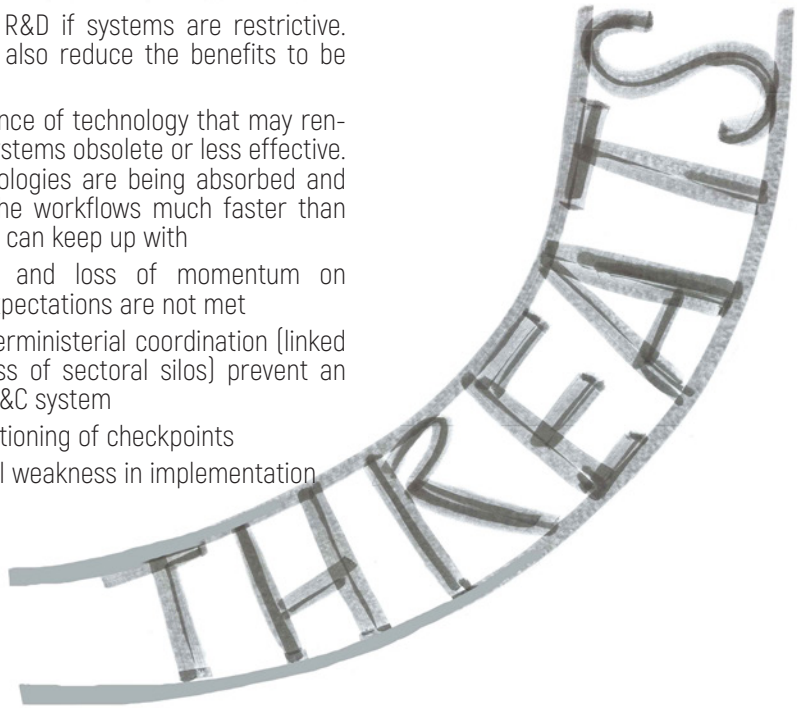
- Recognition of good behavior of users
- Existing technologies, including user mapping and GR flow identification capabilities, for monitoring
- Promote transparent dialogue between multiple actors
- Create useful connections with existing information gathering taking place by users and providers
- Develop a comprehensive approach in the ABS system beyond just monitoring
- Create integrated PIC-MAT-M&C systems
- Position ABSCH as a reliable and authentic source of information. Actors need to know which information can be found on the ABSCH and that it has been verified by relevant authorities.
- Think in a broader and more integral way about access and the benefits arising from it (not just monetary, countries as both users and providers)
- Improve contract management and MAT and generate best practice
- Deepen collaboration between countries (both "users" and "providers")
- Regulators / academia / legal experts are having ongoing discussions and exchange which is an opportunity to make the system work

SWOT Analysis of current status of Monitoring and Compliance systems

Throughout the discussion, it was also apparent that a good indicator of success in the development of M&C systems is to see that there is an increasing number of stakeholders coming into the system.



- Use of complex terminology ("UN jargon")
- Sectoral silos
- Still limited use of the ABSCH
- Handling genetic resource information involved vast volumes of data
- Diversity in approaches (e.g. scope of systems)
- User systems rely largely on designated checkpoints. If users of GR do not pass through the designated checkpoints, there will be no other monitoring.
- Limited knowledge of user patterns and streams of utilization
- Limited resources for implementation
- Mismatch between users and providers in terms of understanding the key ABS concepts
- It seems to be easy not to comply



- Irregular data quality
- Vast amounts of information create a risk of overwhelming regulators and the national authorities
- Diversity in scope across systems
- Duplication of efforts in monitoring across countries
- Commercial providers of information undermine ABSCH
- Risk of a race to the bottom in regulations
- Workarounds to regulation due to partial ratification
- Expectations from M&C systems can be unduly high (e.g. expectations of provider countries about what is being monitored in user countries)
- Threats to R&D if systems are restrictive. This would also reduce the benefits to be shared
- Rapid advance of technology that may render M&C systems obsolete or less effective. New technologies are being absorbed and built into the workflows much faster than regulations can keep up with
- Frustration and loss of momentum on ABSCH if expectations are not met
- Lack of interministerial coordination (linked to weakness of sectoral silos) prevent an effective M&C system
- Wrong positioning of checkpoints
- Institutional weakness in implementation

CONCLUSIONS AND NEXT STEPS

The implementation of the Nagoya Protocol by establishing Monitoring and Compliance measures in a number of countries as well as the issuing of the first IRCCs is a positive development that has opened the possibility to build a coherent and integrated system that takes into consideration the various streams and patterns of utilization of genetic resources. Previous attempts to implement ABS provisions had been centered around regulating the point of access, often resulting in costly and restrictive systems.

The entry into force of the EU regulation on ABS has changed user behavior and raised awareness and interest by users to comply.

The discussions during the two-day workshop have also shown that there is much work to be done and that while the lessons from the implementation of M&C provisions are only now starting to emerge, there is much need for further collaboration and dialogue.

Some of the key conclusions from the discussions are:

- There is a need for user countries to establish compliance measures under Article 15-17 of the Protocol, even in countries that may also be significant providers.
- Most users want to comply and require clarity about their rights and obligations. To that end, we need to encourage further progress in the establishment of measures to provide legal certainty, clarity and transparency of their domestic ABS legislation or regulatory requirements and encourage the issuing of more IRCCs.
- Such integrated system can only emerge through individual country measures emerging in a coherent way. While the various approaches being tried by countries offer the possibility of further learning, they also pose the risk of undermining the effectiveness or efficiency of the overall M&C system. Some standardization and common approach is desirable.
- With regards to the establishment of checkpoints, there is a risk that users may never pass through them, creating loopholes that can reduce the effectiveness, hence the need to position them strategically.
- The ABSCH is an underutilized asset. In part, there is still a significant need for capacity building on the ABSCH. While the SCBD has a special role to play in addressing this, capacity building partners can provide useful technical support to countries as part of their activities. In addition, the interoperability of the ABSCH with other systems (databases) needs to be examined in order to ensure that they are mutually supportive and complementary.
- Technology offers significant opportunities (e.g. for mapping use of GR) to enhance monitoring that must be utilized. At the same time, technology also poses a threat to the extent that regulation does not anticipate new patterns of utilization and is updated accordingly, hence the need for regulators to update themselves on technological trends. Beyond just tracking IRCCs, complementary monitoring efforts, like the ones presented in the workshop, can assist in identifying new trends and patterns in utilization. In these efforts, there is also scope for further integration of information systems, and there is the possibility to integrate users in monitoring and compliance efforts through specific user platforms, exploring tools that have already been developed.
- It is important to make good use of MATs. Considering the central role of MATs for benefit-sharing and the importance of ensuring that they are able to address the diversity of and potential changes in utilization patterns, it would be also very useful to develop standard clauses.
- There is also a need to anticipate ways to address the potential complexities associated with managing multiple contracts over the same resources.

Finally, the workshop reaffirmed the value in exploring ways to maintain an open technical dialogue on the issues highlighted above as countries advance in the implementation of their domestic regulations.

ANNEX 1
AGENDA

THURSDAY, 3 NOVEMBER 2016	
SCHEDULE	**ACTIVITY**
07:30 – 08:30	Registration
08:30 – 09:00	Opening · SEMARNAT/CONABIO · GIZ · CBD Secretariat
09:00 – 09:30	Introduction · Presentation of the agenda · Introduction of participants *ABS Capacity Development Initiative*
09:30 – 10:15	Setting the stage · Technical discussion paper on Monitoring and Compliance *Biodiversity Governance Project, GIZ/CONABIO*
10:15 – 11:00	Utilization of genetic resources · Understanding access patterns, chains of utilization, and sectoral user specificities *Inputs by: Pierre du Plessis, Suhel al-Janabi (ABS Initiative)* *Paul Oldham (One World Analytics)*
11:00 -11:30	Coffee break
11:30 – 13:30	Establishing compliance measures – approaches and experiences · Similarities / differences in implementing Nagoya Protocol requirements: institutional frameworks, establishment of checkpoints, definitions, enforcement mechanisms, etc. *Inputs by: Valerie Normand (SCBD) – AB Clearinghouse and the concept of the NP compliance mechanism* Country Presentations *Jose Luis Echeverría (Guatemala)* *Lactitia Tshitwamulomoni (South Africa)* *Alejandra Barrios / Rosalinda González Santos (Mexico)* *Henry Philippe Ibañez Novion (Brazil)*
13:30 – 15:00	Lunch
15:00 – 17:00	Establishing compliance measures – approaches and experiences (continued) Presentations / Input by Users *Alicja Kozlowska (European Commission)* *Thomas Greiber (Germany)* *Noemie Gonseth (Switzerland).* *Katie Beckett (UK)* *Group work*
17:00 – 17:30	Establishing compliance measures – approaches and experiences *(ctd')* · *Report back to plenary* · *Identification of key findings*
17:30	Closure of day

FRIDAY, 4 NOVEMBER 2016	
SCHEDULE	**ACTIVITY**
08:00 – 09:00	Registration
09:00 – 11:00	Country and institutional experiences in monitoring the utilization of GR Complementary monitoring of the utilization of GR and associated traditional knowledge · *Andrés Valladolid, Perú* · *Tom Suchanandan, South Africa* · Chris Lyle, Natural History Museum (UK) Plenary discussion (facilitated by ABS Capacity Development Initiative)
11:00 – 11:30	Coffee break
11:30 – 13:00	Linking monitoring and compliance with PIC, MAT, utilization, commercialization and benefit-sharing · *Pierre du Plessis (African Union Commission)* · *Paul Oldham (One World Analytics)*
13:00 -14:30	Lunch
14:30 – 16:00	Key findings, recommendations and opportunities for cooperation – This session will include a discussion of the key opportunities for international cooperation / harmonization of monitoring and compliance approaches. *Group work*
16:00 – 16:30	Coffee break
16:30 – 17:00	Key findings (continued) *Report to plenary*
17:00 – 17:30	Conclusions and next steps & Closure

ANNEX 2
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WORKSHOP REPORT

MONITORING & COMPLIANCE
UNDER THE NAGOYA PROTOCOL