**Suhel al-Janabi, Ute Feit, Eva Fenster,
Thomas Greiber and Peter Schauerte (Eds.)**

Vilm ABS Dialogue 2018 – Informing about Domestic Measures for Access to Genetic Resources

Final Report

Presenting Countries: Antigua and Barbuda, Benin, Bhutan, Dominican Republic, Ecuador, France, Guatemala, Madagascar, Malaysia, Republic of Seychelles, Uganda

Access Profile

Criteria	Acquired information
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	
Specific access regulation	
Specific access procedures (law or any defined process) for non-commercial use	
English translation for users	
Visualization of ABS procedure	
Information on access procedure / regulations accessible through web-link	

Federal Agency for Nature Conservation

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2019

Vilm ABS Dialogue 2018 – Informing about Domestic Measures for Access to Genetic Resources

Report of an International Meeting hosted by the Nagoya CNA-Unit of the German Federal Agency for Nature Conservation on the Isle of Vilm, Germany, 10 - 14 September 2018

Presenting Countries: Antigua and Barbuda, Benin, Bhutan, Dominican Republic, Ecuador, France, Guatemala, Madagascar, Malaysia, Republic of Seychelles, Uganda

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List of Abbreviations

ABS	Access and Benefit Sharing
ABS-CH	ABS Clearing House
aTK	Associated Traditional Knowledge
BfN	Federal Agency for Nature Conservation
CBD	Convention on Biological Diversity
CNA	Competent National Authority
COP	Conference of the Parties
EC	European Commission
GR	Genetic Resources
IPLCs	Indigenous Peoples and Local Communities
IRCC	Internationally Recognized Certificate of Compliance
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
NFP	National Focal Point
PIC	Prior Informed Consent
R&D	Research and Development
SCBD	Secretariat of the Convention on Biological Diversity
TK	Traditional Knowledge

1 Background

After entry into force of the Nagoya Protocol and the corresponding Regulation (EU) No. 511/2014, European users of genetic resources (GR) are required to "exercise due diligence" to ensure that they have acquired GR or associated traditional knowledge (aTK) in accordance with the national access procedures of the respective provider country. In Germany, as in other EU member states, “competent national authorities” (CNAs) for Access and Benefit Sharing (ABS) are in the course of formation and a first meeting of European CNAs already took place in March 2017 on Vilm-Island. One of the discussed implementation challenges was the availability of transparent and reliable national access regulations in provider countries. CNAs, as the German Nagoya CNA-Unit, are repeatedly being asked for information and advice in this regard. But the ABS Clearing House (ABS-CH), designed as the key tool for information exchange aiming at enhancing legal certainty, clarity, and transparency on procedures for access to GR, is not yet sufficiently populated and thus does not allow users to gather the relevant information for the vast majority of countries.

To foster the process of implementing the Nagoya Protocol, the Nagoya CNA - Unit of the German Federal Agency for Nature Conservation (BfN) has organized a series of two international ABS dialogues (August 2017 and September 2018) at the International Academy for Nature Conservation on the Baltic Sea Isle of Vilm, Germany. The dialogues aimed to provide an opportunity to identify and present best-practices on available, clear and transparent access regulations with representatives of CNAs/NFPs of provider countries. In this sense, the objective of the meetings was not to promote facilitated access, but rather to secure transparency, in order to allow users of GR to be better informed by European CNAs towards countries that have structured, clear, and transparent access measures in place.

To identify countries that already have such access procedures in place, BfN commissioned two overview studies to guide the selection and invitation of approximately ten providing countries for both ABS Dialogues on Vilm-Island in August 2017 and September 2018.

Based on the results of the first study that was undertaken in 2017, the following eleven countries (mostly ABS NFPs and representatives of the CNAs) were invited to present their respective access procedures: Australia, Brazil, Costa Rica, Ethiopia, India, Kenya, Mexico, Peru, Philippines, South Africa and Viet Nam.

While these countries may be considered as “champions” of ABS implementation with respect to access regulations, it can be concluded from the first ABS Dialogue and moreover from its underlying scoping study that the overall number of countries with functioning, clear and transparent access measures in place is still very limited. In this regard the ABS Dialogue 2017 convening the positive tip of the ABS implementation iceberg was thus only a first step towards more ABS transparency and legal certainty. However, it provided a great exchange, discussion and documentation opportunity with respect to important state of the art access regulations.

Consequently, BfN has organized a second ABS Dialogue of the same kind in September 2018 (September 10 -14) which gave further countries being comparatively advanced in implementing the Nagoya Protocol the opportunity to present and discuss their current access conditions to GR.

As in the previous year, the output of the 2018 meeting is a report and a publication in the BfN conference volume compiling e.g. a summary table of the presented access proce-

dures. The report of the first dialogue in 2017 can be downloaded under https://www.bfn.de/fileadmin/BfN/service/Dokumente/skripten/Skript485.pdf.

A key criterion for the selection of countries was the ratification of the Nagoya Protocol. Other important criteria were the existence and implementation of clear and transparent national procedures, including defined designated institutions that are regulating the access to GR in the given country. Furthermore, the need to ensure a balanced regional representation in the selection of the provider countries at the respective dialogues was emphasized.

In 2017, an access profile template for summarizing the most relevant information on the respective ABS systems per country was developed. This template was also used for the 2nd ABS Dialogue. The ABS-CH (https://absch.cbd.int/) was then used to scan all parties of the Convention on Biological Diversity (CBD) to identify countries that already have published ABS measures. The available measures were studied and the information was fed into the template for the access profiles.

The analysis of the access profiles and the accompanying exchanges with the short-listed countries were thus narrowed down to eleven countries that went through the full registration process for the dialogue. The following eleven countries (mostly ABS NFPs and representatives of the CNAs) were invited to present their respective access procedures in 2018: Antigua and Barbuda, Benin, Bhutan, Dominican Republic, Ecuador, France, Guatemala, Madagascar, Malaysia, the Republic of Seychelles and Uganda.

This report is based on various notes taken during the workshop. It does not purport to reproduce at full length all debates and interventions. The summarized discussion-points are based on notes taken during the meeting and do not necessarily reflect the official position of the respective countries.

Participants

The ABS Dialogue on the Isle of Vilm brought together around 35 representatives from 16 countries in Asia, Europe, Latin America and the Caribbean. These included ABS National Focal Points (NFPs) and CNAs, representatives from the European Commission (EC), the Secretariat of the Convention on Biological Diversity (SCBD) and the ABS Capacity Development Initiative.

For further details, a list of participants is attached in the annex.

2 Opening Remarks: The Journey Implementing the Nagoya Protocol

Opening remarks at the ABS Dialogue were held by representatives from the BfN, the SCBD and the EC.

They were preceded by a warm welcome on the first evening through the representative of the initiating institution of the conference, Mrs. Ute Feit, Legal Officer at the BfN. Mrs. Feit informed in her presentation about the objectives of the ABS Dialogue and underlined that beside the very helpful joint creation of the access profiles the dialogue will above all promote a deeper and better communication and cooperation between CNAs of provider and user countries. Mrs. Feit introduced and thanked the GeoMedia team for its support in organizing this event.

On the second day and on behalf of the BfN, Mr. Thomas Greiber, Head of the German

CNA for the Nagoya Protocol which forms part of the BfN, welcomed all participants to the ABS Dialogue 2018. In his opening speech, Mr. Greiber informed the group about the structure of the BfN, highlighting that compliance checks are at the center of the work of the German CNA. He further underlined the importance of the ABS-CH and an open flow of communication among the CNAs of provider and user countries.

The presentation of Beatriz Gomez, Programme Officer for ABS at the SCBD, addressed some of the outcomes of the analysis conducted for the first assessment and review of the effectiveness of the Protocol to be conducted at the Third meeting of the Conference of the Parties (COP) serving as the meeting of the Parties to the Nagoya Protocol on ABS in Egypt this year. Mrs. Gomez presented an overview of progress made by Parties in establishing institutional structures and adopting ABS measures to implement the Protocol, as well as progress made in populating the ABS-CH. The presentation also provided information on activities carried out by the CBD Secretariat to support the implementation of the Protocol.

Alicja Kozlowska, Policy Officer for ABS under the Nagoya Protocol at the EC reported on the developments at the level of the European Union, focusing on EU Regulation No. 511/2014 and the users' due diligence obligation. In particular, she highlighted the need for ABS awareness-raising by CNAs and the importance of exchange between user and provider countries.

3 Agenda, Objective and Work Flow of the Workshop

The moderator Mr. Peter Schauerte gave participants a brief overview of the agenda (see annex XI - XVII). He highlighted that the objective of the dialogue is to gather a better knowledge base on existing regulations and access procedures while fostering transparency for both, countries using and providing GR. This will especially allow European CNAs to inform and guide users of GR towards countries that have clear and structured access measures in place.

After the presentation of the agenda, a block of 90 minutes was foreseen for each of the 10 countries to present and discuss their respective access procedures. The first 50 minutes were used for the presentation of the access procedures, including questions and answers. In the third and last block of 30 minutes, the prepared access profile was presented, amended and validated by each country, summarizing the key features of the respective ABS systems.

The third and last block of 20 minutes was used to introduce a fictional access scenario and to project this scenario onto the respective ABS system.

On the evening of the third day, a peer-to-peer exchange took place. Participants were invited to discuss ABS topics of special interest in more detail. The following topics were proposed and chosen by the participants and then discussed in three groups:

- The ABS-CH mechanism
- CNA cooperation
- Harmonised terminology

On the fourth day and after all countries had discussed their access procedures, the results of the peer-to-peer exchanges were briefly presented by members of the respective groups,

followed by an overall discussion. It allowed identifying key access questions and options for addressing them. The importance of communication and exchange with users was also underlined. At last, options for further CNA cooperation and the activities foreseen by the SCBD were presented.

4 Country Session

Country presentations aimed to give relevant ABS actors the opportunity to present their national access procedures.

Following the country presentations, presenters were given time to clarify questions of understanding. The questions posed by participants focused in particular on:

- The legal framework for ABS implementation
- The institutional set-up with regards to ABS-compliant access to GR / aTK
- What is required to access GR / aTK in the respective countries (e.g. Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), collaboration with national research institutions, permits, etc.)
- Differences between access for commercial and non-commercial purposes
- Step-by-step procedures and timelines for access to GR / aTK

5 Access Procedures of Antigua and Barbuda

Ms. Helena Brown, Technical Coordinator, Department of Environment, Ministry of Health, Wellness and the Environment

Ms. Nneka Nicholas, Technical Officer / Legal Consultant, Department of the Environment, Ministry of Health, Wellness and the Environment

Fig. 1: Ms. Nneka Nicholas and Ms. Helena Brown

5.1 Country Presentation

Setting the context

Antigua and Barbuda ratified the CBD in March 1993 and became a Party to the Convention in the same year. Antigua and Barbuda deposited its instrument of ratification for the Nagoya Protocol on December 12th, 2016, which came into force on March 12th, 2017.

The main drivers of the process to implement the Nagoya Protocol stemmed from the desire to protect our biodiversity. This is especially after the negative experiences of nearby Caribbean countries, who had lost access and benefits to their GR. Additionally, Antigua and Barbuda has always encouraged environmental research on our islands to inform us about the indigenous flora and fauna. Therefore, ratifying the Nagoya Protocol seemed to be the natural pathway to ensure that the citizens continue to have free and fair access to the benefits of our GR while at the same time allowing international researchers to access and to assist in gathering knowledge on the indigenous flora and fauna.

Legal framework for ABS implementation

The essence of the legal framework for ABS implementation is found in Section 67, of the Environmental Protection and Management Act, 2015 and is as follows:

> "It is noted under this Act that the Government of Antigua and Barbuda together with the civil society exercises sovereign rights over the biological resources existing in the country and recognises that it is the duty of the state and its citizens to regulate

the access to biological resources as well as related use of community knowledge and technologies."

The entire framework is laid out in Sections 67 – 73, whereby the requirements for PIC and MAT are included.

Institutional framework for ABS implementation

Prior to 2015, Antigua and Barbuda had no legal framework for the processing of access requests. During that time, soft policy practices were relied upon that resulted in difficult to monitor agreements.

Development and consultations on the Environmental Protection and Management Bill began in 2005. After ten years of inter-agency and public consultations, in May 2015 the Environmental Protection and Management Act (EPMA) was passed.

Sections 67 – 73 of the EPMA, 2015, speak to accessing GR and their aTK in Antigua and Barbuda. These sections specifically highlight Article 15 (benefit sharing) and 8j (preservation and maintenance of knowledge, innovations and practices of indigenous and local communities) of the CBD.

The Government of Antigua and Barbuda has the exclusive rights to grant access to GR. The Department of Environment (DoE) is the CNA. The DoE has developed Model ABS Agreement templates which contain elements of PIC and MAT.

All researchers must submit an application which is reviewed by the CNA. The DoE consults an informal committee to work out the details of PIC and MAT as well as assess the merits of the application along with the documents submitted with it. The Committee would consist of the relevant government agencies and informal community groups from which the GR may be derived. The DoE then finalises the details of PIC and MAT within the agreement.

The agreement must be signed before GR are taken out of the country. Presently, the legislation is being reviewed to expand on the procedure in more detail.

With regards to penalties, the measures include a perpetual ban on collecting resources, confiscation of GR and / or global publication of offence (usage of reporting tools on the CBD database / CHM). The DoE is the publishing authority on the CBD ABS-CHM.

Community Groups and Informal Groups act as Informal Internal Access Checkpoints for DoE. They report sightings of persons collecting our genetic material, ensure that persons who are collecting genetic material have permission to do so and point them in the direction of the relevant authorities. Other government Agencies (such as the Ministry of Foreign Affairs) also provide this Informal Internal Access Checkpoint function for the DoE.

Steps to access GR and aTK

It is important to note that both the commercial and non-commercial access is the same, there is no difference.

Step-by-step procedures for access to GR / aTK:

1. The User may gain access via Govt Agencies (Min of Foreign Affairs), website (to be developed), local Universities, Environmental NGOs, or go directly to the DoE (Focal Point and CNA).
2. Once the DoE receives the request, the Informal Committee is convened to discuss the

details of the application.

3. If the application is approved, a draft agreement is sent to the user.
4. The DoE then issues a permit to collect the GR.
5. The User collects the samples of GR and brings it back to the DoE.
6. Inspection of the samples occurs and the Agreement is signed and issued. Additionally, the Export Certificate is issued by the appropriate authority.

Presently, there are no timelines that have been set. These are being developed in the Regulations.

Presently, Antigua and Barbuda are part of the project “Advancing the Nagoya Protocol in Countries of the Caribbean Region” IUCN/UNEP project. Some of the outcomes of this project include the development of Regulations for the ABS section of the EPMA, the development of a policy for ABS with the assistance from the DoE and the Technical Advisory Committee. These are being crafted to complement Antigua and Barbuda’s NBSAP.

Implementation experiences and outlook

Benefits:

Section 76 of the EPMA calls for the creation and maintenance of a Natural Resources Inventory. Antigua and Barbuda does not have the resources to complete this adequately. Therefore, we actively encourage researchers to assist with this process of gathering data about the flora and fauna and also conservation data. These researchers receive permits from the DoE. While conducting the research they are accompanied by a member of the DoE or the informal committee. The DoE creates research opportunities for students pursuing tertiary level education alongside these international researchers where possible. The DoE has worked closely with researchers to populate its Natural Resources Inventory with respect to the Magnificent Frigate Bird in Barbuda and Endemic Lizards on Redonda.

Challenges:

Some GR are sold as souvenirs (such as plant seed pods and conch shells) and are therefore, difficult to monitor once they are purchased and leave the country in suitcases.

The ABS agreement is between the Government of Antigua and Barbuda and the research institution represented by an individual. Therefore, we have to assume the researcher is trustworthy and will keep their end of the agreement. This is a risk that the DoE has to assume.

Although we have had no experience in this area as yet, securing monetary benefits from researchers may be difficult. Additionally, calculation of the value of GR and Traditional Knowledge (TK) for commercial purposes may prove to be a challenge.

Monitoring the status of our GR is necessary as we cannot protect what we are not aware of but the process is human resource intensive. Working with students and researchers is one way to assist in achieving this.

Antigua and Barbuda and the rest of the Caribbean share similar GR which complicates the discussion of TK within the country and the region. Therefore, we have engaged with various countries of the region, most notably through the CARICOM Secretariat, to come up with solutions to move forward jointly.

Antigua and Barbuda does not have indigenous peoples and there is no legal recognition of communities, that is, the boundaries are not clearly defined. This is with the exception of Barbuda where it is unlikely to be a major difference between the biodiversity or TK. Therefore, the DoE has to be the ultimate agency to represent local communities in the negotiation of MAT with respect to both GR and TK. In these cases, the representatives of the local communities are invited to be part of the informal committee to discuss the details of the MAT.

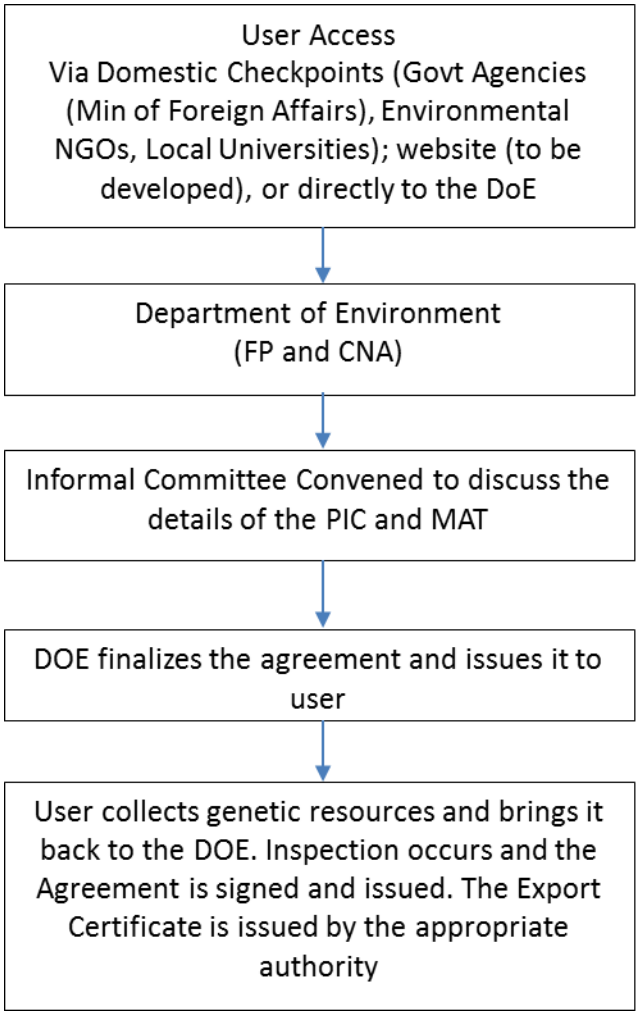


Fig. 2: Flow Chart Antigua and Barbuda

5.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- Antigua and Barbuda use the term “checkpoint” for their national access controls (e.g. tour operators and government agencies). They are no checkpoints as foreseen in Article 17 of the Nagoya Protocol and there is no legal framework for compliance yet.
- The application procedure for access to GR in Antigua and Barbuda does not differentiate between commercial and non-commercial use. However, commercial users are obliged to submit environmental impact assessments.

- Timelines for the ABS process in Antigua and Barbuda are not yet defined. They are in the process of being discussed and finalised under the IUCN ABS project in the Caribbean.
- As in other countries, “jurisdiction shopping” for transboundary resources is a problem in the Caribbean. To avoid jurisdiction shopping in the region, authorities in Antigua and Barbuda held first talks with other Caribbean countries concerning a regional harmonization. The idea is to create a specific site where users can retrieve relevant information on ABS processes in the Caribbean region.
- The issue of “jurisdiction shopping” for transboundary resources is inherent in the system because it is human behaviour to try to find the easiest and cheapest way to access resources. Harmonised measures for access to GR may be a viable solution.
- Antigua and Barbuda has undertaken efforts of involving community groups in ABS projects. Although Antigua and Barbuda often engages with communities, much work remains to be done.
- The ABS legal framework of Antigua and Barbuda applies to terrestrial and marine resources.
- Provider countries such as Antigua and Barbuda should inform the CNAs of user countries in case they detect the misappropriation of GR.
- When a user accesses GR or aTK in Antigua and Barbuda, he or she only needs to contact the Department of Environment at the front end because this Department leads the ABS process. The relevant community will be part of this process through an informal committee at the back end.

5.3 Access Profile

Tab. 1: Access Profile Antigua and Barbuda

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	Yes	Ratified December 2017	
Signatory	Yes	As above	
NFP (National Focal Point)	Ms. Diann Black-Layne		
Contact NFP	dcblack11@gmail.com doe@ab.gov.ag antiguaenvironmentdivision@gmail.com +1 268 462 4625, +1 268 562 2568		
CNA (Competent National Authority)	doe@ab.gov.ag antiguaenvironmentdivision@gmail.com +1 268.462.4625		

Criteria	Acquired information	Comments	Source
Contact CNA	doe@ab.gov.ag antiguaenvironmentdivision@gmail.com +1 268.462.4625		
CNA Deputy	No		
Contact CNA Deputy	Telephone Email	N/A	
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	Yes	Department of Environment	
ABS law	Yes	Enshrined within the Environmental Protection and Management Act, 2015 (s 67 – 73)	http://laws.gov.ag/acts/2015/a2015-11.pdf
Specific access regulation	No	Access regulation in draft form is in progress.	
Specific access procedures (law or any defined process) for non-commercial use	No		
English translation for users	Yes		http://laws.gov.ag/acts/2015/a2015-11.pdf
Visualization of ABS procedure	No	Planned for the future	
Information on access procedure / regulations accessible through web-link	Yes		https://environment.gov.ag/laws-education#laws/procedures

Criteria	Acquired information	Comments	Source
Access demand form	Yes		https://environment.gov.ag/laws-education#forms/Access-to-the-Genetic-and-Biological-Resources-in-Antigua-and-Barbuda
Specific access demand form for non-commercial purposes	No	Same for commercial and non-commercial use of GR.	
Online application system	No	Signed application must be sent to NFP.	
Compulsory documents for access demand application	Yes	Research proposal (including reason for research and methodologies) Letter from head of research institution Environmental Impact Assessment (if requested) Declaration of Truth	
Submission of access application at	Name of institution	Department of Environment	
Access fees	No	Access fees are in progress.	
Other permits prerequisite to obtain ABS permit	Yes	Phyto-sanitary certificate and export permit (needed during ABS permit)	
IRCC (Internationally Recognised Certificate of Compliance)	Yes		
Have ABS permit(s) been issued in the country?	Yes		
ABS permit(s) issued by	Name of institution	Department of Environment	

Criteria	Acquired information	Comments	Source
Average timeline (from access demand to permit)	Timeline not defined		
MAT(s) signed	Yes		
MAT(s) to be signed with	Name of entity	Department of Environment on behalf of the Government of Antigua and Barbuda	
Standard MAT clauses	Yes		
PIC(s) granted	Yes		
PIC(s) to be granted by	Name of entity	Department of Environment	

5.4 Access Scenario Discussion

Tab. 2: Access Scenario Discussion Antigua and Barbuda

Case	Parameter of the case	
A domestic trading company informs the ABS authority in your country about its intention to buy a specific variety of fruits from farmers. The fruits are harvested from trees growing on Crown land as well as on private land of farmers. The domestic company exports the fruits to a cosmetic company in an EU member state that undertakes own Research and Development (R&D) with the oils of the fruits to develop new cosmetics.	**user**	cosmetic company
	commercial or non-commercial intent	Commercial
	is the user from a party	Yes
	provider in country	Farmers
	other actors involved	trading company
	IPLCs involved	Yes
	aTK	No
	location of access	Crown, communal and private land / in situ

In this scenario, the users of the GR would be the cosmetic company situated in an EU member state and the intent would be commercial use. The user, being located in an EU member state, would be considered a party to the Nagoya Protocol. The providers in the country would be the farmers from whose land the fruits were harvested as well as the Government of Antigua and Barbuda as the second source was Crown land. The other actors involved would be the domestic trading company who would have supplied the cosmetic company with the fruits. Local communities would be involved as they would live around the land areas where the fruit is harvested. It could be said that aTK was used in the creation of this product. It could be assumed that they would have received information that the oil was used by local actors who would have used it for cosmetic reasons. The location of access took place on Crown and private land in situ.

Were this scenario to occur in Antigua and Barbuda, the Government agent with the author-

ity to grant phytosanitary export certificates, the Plant Protection Unit, would ask the domestic trading company to whom they would be selling the fruits. If honest, the regular procedure for ABS would apply which would be as follows:

- User Access via Govt Agencies (Min of Foreign Affairs), website (to be developed), Universities, Environmental NGOs, check points
- Department of Environment (NFP and CNA)
- Informal Committee convened to discuss the details of the application
- If application approved, draft agreement sent to user
- DoE issues permit to collect
- User collects GR and brings it back to the DoE.
- Inspection occurs and the Agreement is signed and issued. Additionally, the Export Certificate is issued by the appropriate authority.

However, if the domestic trading company chose to not disclose to whom they were supplying the fruit, no red flags would be raised as this is simply a trade transaction for commodities. This could be considered a loophole and Antigua and Barbuda would have to rely on EU law and measures to assist with compliance and enforcement.

The CNA, the DoE, would first try and contact the company marketing the cosmetic products to come to an amicable understanding about the way forward with the GR before proceeding to enacting the penalties.

6 Access Procedures of Malaysia

Ms. Siti Nurzaliana Mohd Safari, Assistant Secretary, Biodiversity and Forestry Management Division, Ministry of Water, Land and Natural Resources

Mr. Chitdrakantan Subramaniam, Principle Assistant Secretary, Biodiversity and Forestry Management Division, Ministry of Water, Land and Natural Resources

Fig. 3: Mr. Chitdrakantan Subramaniam and Ms. Siti Nurzaliana Mohd Safari

6.1 Country Presentation

Background

According to a study conducted by Conservation International in 1997, Malaysia is recognized as one of the twelve megadiverse countries. Therefore, as a megadiverse country and in line with the country's commitment to preserve its biodiversity, Malaysia ratified the CBD in 1994. Malaysia is still not a party to the Nagoya Protocol, however plans to accede to the Protocol once the domestic ABS legislations are in force.

Reconstituted in 1963, Malaysia practices Parliamentary Democracy with a constitutional monarchy system where the Federal Constitution of Malaysia is the Supreme Law. Under the Federal Constitution, matters relevant to biodiversity falls under the jurisdiction of the Federal and State Governments. Some subject matters relating to natural resources such as land and forests are under exclusive jurisdiction of the State Government.

Legal framework on ABS

No specific regulatory measure on ABS is in place for all states in Peninsular Malaysia and the Federal Territories, except for the state of Sabah and Sarawak. As a way to monitor research activities in Malaysia undertaken by foreigners, the government has introduced the "General Circular No.3 1999 Undertaking Research in Malaysia" where foreign researchers who wish to conduct a non-academic research in Malaysia are required to apply for a research pass. Furthermore, researchers (both local and foreigner) are also required

to abide to existing biodiversity related laws to access biological resources in Malaysia.

The states of Sabah and Sarawak are more advanced on matters relating to ABS since these states have established their own ABS regulatory measures which are currently in force: Sabah Biodiversity Enactment 2000 and Sarawak Biodiversity Ordinance with Amendments 2014, respectively. Further information on ABS regulatory measures in the state of Sabah and Sarawak can be found in the Malaysia Access Profile and in their respective portals;

In order to fulfill Malaysia's commitment to the CBD and in preparing for Malaysia's accession to the Nagoya Protocol, Malaysia has gazetted the Access to Biological Resources and Benefit Sharing Act 2017 [Act 795] which is still not operational at the moment. The Act clearly delineates the jurisdiction between Federal-States, where the State government shall implement the Act while the Federal government shall coordinate the implementation of the Act. The Act shall be enforced in Malaysia with different dates of entry into force for Sabah and Sarawak, subject to the approval of the respective State Authority. The Act must be read together with existing written law relating to ABS and be in addition to the provisions in any other law relating to biodiversity.

The main objective of the Act is to regulate access to biological resources and associated TK while ensuring the country receives benefits from their utilisation.

The scope of the Act includes biological resource (GR, derivatives including information and biochemical compounds) and aTK.

According to the Act, access is defined as the taking of a biological resource from its natural habitat, or place where it is kept, grown, or found including in the market, for the purpose of R&D. Access activities exempted under the Act among others include:

- fishing for commerce, recreation or game
- taking animals or plants for food
- taking biological resources that has been cultivated or tended for any other purpose other than for R&D
- taking natural produce including oil and honey for any purpose other than R&D
- collecting plant reproductive material for propagation
- carrying out commercial forestry
- use and exchange among Indigenous Local Communities (ILCs) in the exercise of their traditional and customary practices; and
- access to biological resource exempted under section 60 of the Act

Institutional framework on ABS

The institutional framework for ABS in Malaysia comprises the following: National Competent Authority (NCA): the overall coordinating body of Act 795 and the NFP to CBD and Nagoya Protocol; Competent Authority (CA): the implementing body of Act 795 (as listed in the First Schedule of Act 795); Advisory Committee: established by NCA - providing advice to NCA and CA on scientific, legal, technical, ethical and other relevant disciplines related to ABS; Advisory body: providing advice to CA on matters relating to ILCs and aTK; Committee: established by CA - assisting CA in carrying out its function; checkpoints: Intellectual

Property Corporation of Malaysia, National Pharmaceutical Regulatory Agency; Public funding office (research grant), National Institute of Health and public research universities; Malaysia ABS-CH portal: online application and for monitoring and tracking purpose.

Steps to access biological resources and aTK in Malaysia:

- All access permit application must be submitted to the CA;
- Access permit is the proof that PIC (if aTK is accessed) and benefit sharing agreement (R&D for commercial / potential commercial purpose) / statutory declaration (for R&D non-commercial purpose) requirements are met;
- Access permit is not transferrable;
- R&D for non-commercial purpose must be done in collaboration with a public higher education institution, public research institution or Government agency unless the CA is satisfied that:
    - the applicant is a non-profit NGO based or registered in Malaysia;
    - local researchers are involved in the activity;
    - a program for capacity building is included in the activity;
- Access permit is **not required** under these conditions:
    - carrying out research for non-commercial purpose (subject to conditions as may be prescribed by CA and PIC from relevant ILCs) by students / staff at public higher education institution, public research institution or government agency;
    - exchanging biological resources between students/staff in the same/between public higher education institution, public research institution or government agency for research for non-commercial purpose;
    - carrying out / continuing research for non-commercial purpose by a third party who access a BR from a permit holder at the request of:
        - permit holder;
        - public higher education institution, public research institution or government agency
    - exemption by Minister

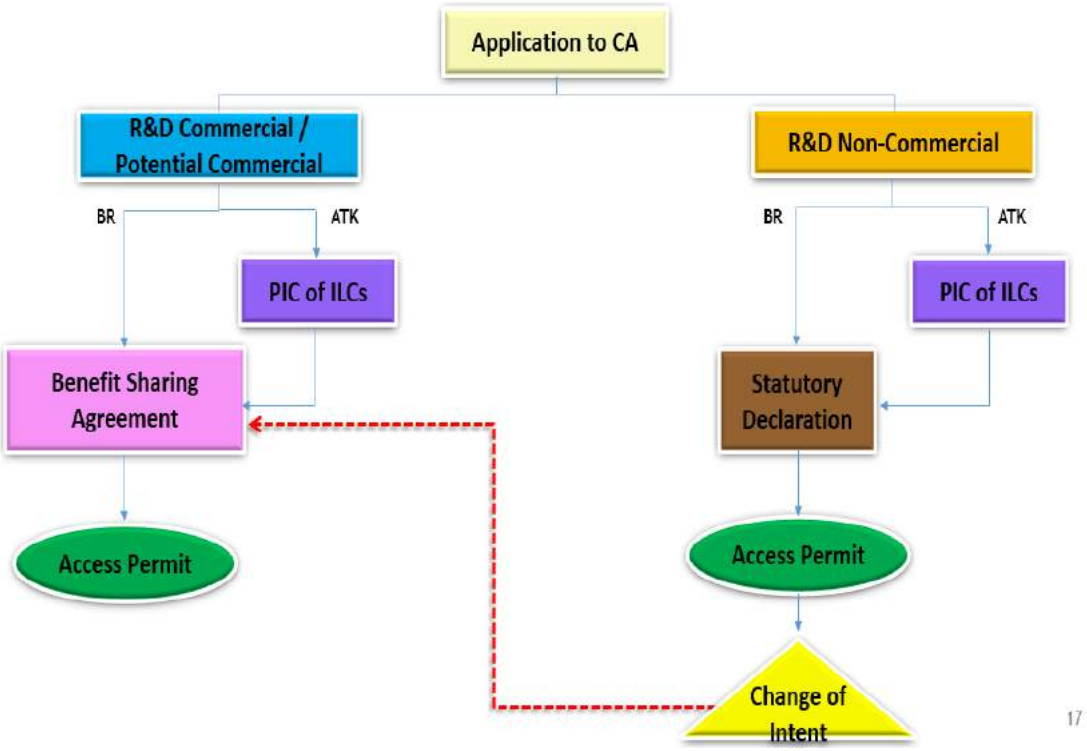


Fig. 4: Steps to access biological resources and aTK in Malaysia

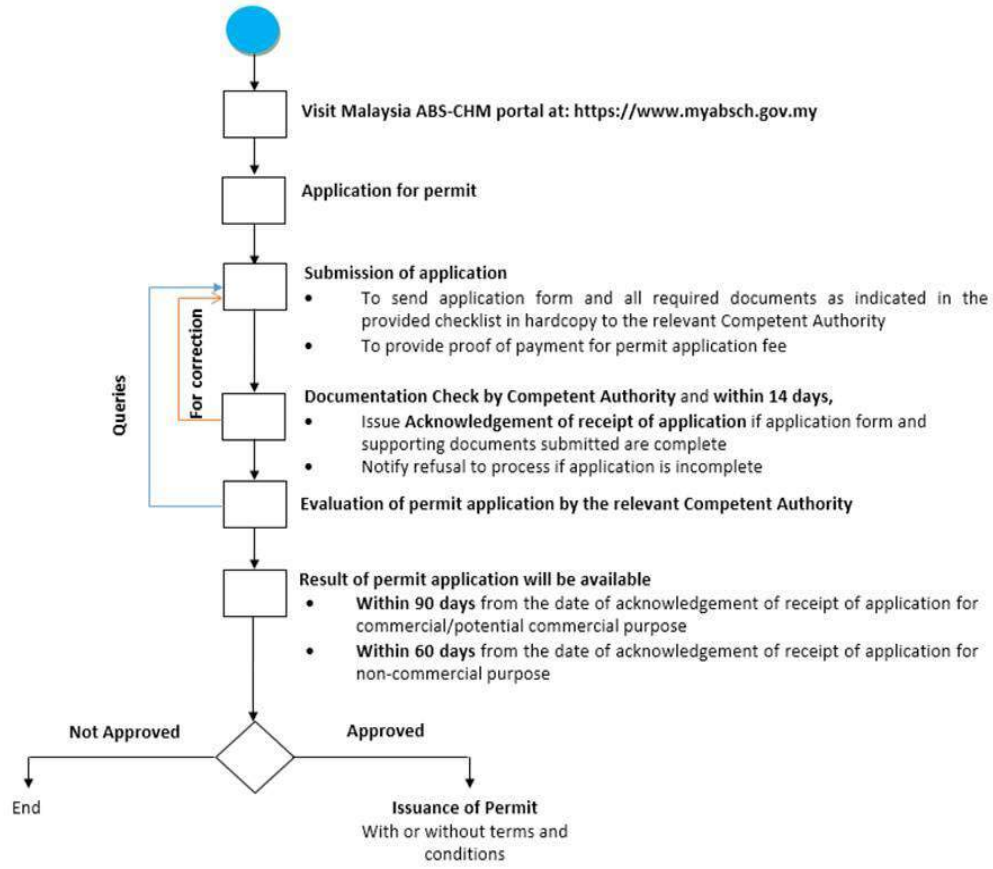


Fig. 5: Flow Chart Malaysia

6.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- If the research results of a student turn out to show a potential of commercialisation, a re-application (for commercialisation) is necessary. Malaysia ensures that users return for renegotiations primarily through user declarations and monitoring exercises.
- Malaysia distinguishes potential commercial research from non-commercial research based on the understanding of the individual applicant. If the applicant thinks that a chance for commercialisation exists, he or she is required to make an application for “potential commercial research”.
- The ABS law in Malaysia is yet to be enforced. Misappropriation of GR / aTK in Malaysia is a criminal offence. Penalties for non-compliance with the law include fines. The prosecution will be done at state level.
- The term “potential commercial research” as mentioned in Malaysia’s Act is quite subjective and could be used as a loophole. The term is not defined in Malaysia’s Act. Malaysia aims to include a definition of this term in its user guidelines, which are currently being drafted.
- It may take up to 60 days to receive a permit for non-commercial purposes and up to 90 days for a commercial permit. MAT is not included in this timeline.
- Some countries develop a national ABS-CH. Malaysia is planning to create a website.
- When IPLCs are not involved in Malaysia, PIC is not required. The permit would be based on MAT only.
- Both biological resources and GR are defined in Malaysia’s Act. If you access material as a commodity, no ABS permit is required.
- Malaysia receives around 200 applications for non-commercial purposes a year.
- If you want to do research in Malaysia, you need to cooperate with a local research institution. It is a strong measure to promote local research.
- Like in Antigua and Barbuda, the Malaysian checkpoints (e.g. IP offices) are internal access control points (their goal is to control the access to and movement and use of domestic GR in their own jurisdiction). They cannot be considered compliance checkpoints as foreseen under the Nagoya Protocol. The Malaysian checkpoints are also listed on the ABS-CH. It would be better to remove this information in order not to confuse users of the ABS-CH. Further, it is important to use common terms to avoid aggregating false data and to come up with a clear terminology that distinguishes between internal access control points and checkpoints as foreseen under the Nagoya Protocol.

6.3 Access Profile

Tab. 3: Access Profile Malaysia

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	No		
Signatory	No		
NFP (National Focal Point)	Dr. Megat Sany Bin Megat Ahmad Supian	Undersecretary Biodiversity and Forestry Managment Division Ministry of Water, Land and Natural Resources	
Contact NFP	dr.megat@kans.gov.my +603 8886 1443	Dr. Megat Sany bin Megat Ahmad Supian Undersecretary Biodiversity and Forestry Management Division Ministry of Water, Land and Natural Resources Tel: +603 8886 1443 Email: dr.megat@kats.gov.my	
CNA (Competent National Authority)	Yes	The Secretary General of the Ministry responsible for natural resources and environment shall be the NCA.	Provision 7 of the http://www.federalgazette.agc.gov.my/outputaktap/aktaBI_20171017_795BI.pdf
Contact CNA	No information		
CNA Deputy	No	CNA Deputy is planned.	
Contact CNA Deputy	Telephone Email	N/A	
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	No	All Competent Authorities must establish an Advisory Body comprising of representatives from the IPLCs. Local Communities would be consulted depending on the type of application by the applicant.	Provision 9 of Act 795

Criteria	Acquired information	Comments	Source
ABS law	Yes	The National ABS law will be enforced once the legislations are ready. Currently, the draft legislations are being reviewed by the Attorney's General Chambers. The State of Sabah and Sarawak have their own biodiversity/ABS related state law which is currently enforced.	National law: http://www.federalgazette.agc.gov.my/outputaktap/aktaBI_20171017_795BI.pdf Sarawak: The Sarawak Biodiversity Ordinance with Amendments 2014 Sabah: Sabah Biodiversity Enactment 2000
Specific access regulation	Yes	Under Act 795, any person who intends to access a biological resource or TK associated with a biological resource must apply for access permit. Note: As the national ABS law is not operational, the existing biodiversity/ABS related laws currently enforced in Malaysia must be complied. Sarawak: Sarawak Biodiversity Regulations, 2016 Sabah: Guidelines on Access/Transfer License application	Part III of Act 795
Specific access procedures (law or any defined process) for non-commercial use	Yes	Under Act 795, for non-commercial purpose: A statutory declaration must be submitted when access application is made. Access for non-commercial purpose must be done in collaboration with a public higher education institution, public research institution or Government agency. Sarawak: As prescribed under Sarawak Biodiversity Regulations 2016 Sabah: All application for access license is subject to security screening	Provision 15, 16 of Act 795

Criteria	Acquired information	Comments	Source
English translation for users	Yes	Also available in Malay language (for Act 795 and Sabah)	
Visualization of ABS procedure	Yes	At the Federal level, it is in preparation. Sabah and Sarawak: already available online	
Information on access procedure / regulations accessible through web-link	Yes	Act 795, the information will be made available in the national ABS portal which is under development. Sabah: Access and Transfer Application Sarawak: http://www.sbc.org.my/our-services/research-permit-application (This portal will also give information on the general process with ABS for Sabah and Sarawak)	
Access demand form	Yes	Act 795: Will be made available online. Sabah: Available online Sarawak: Available online	
Specific access demand form for non-commercial purposes	No	Act 795: The standard form shall be used for non-commercial purposes. Sabah and Sarawak: The standard form as in the regulations/guideline is used.	
Online application system	Yes	Act 795: In planning Sabah: https://sabcapps.sabah.gov.my/index.php Sarawak: In planning	Provision 32 of Act 795
Compulsory documents for access demand application	Yes	Will be made available for the public.	
Submission of access application at	Name of institution	All submission must be sent to the relevant Competent Authorities Act 795, list of CA as prescribed in the Act Sarawak: Sarawak Biodiversity Council Sabah: Sabah Biodiversity Council	First Schedule of Act 795
Access fees	Yes	Act 795 and Sabah: Yet to be implemented Sarawak: Yes	

Criteria	Acquired information	Comments	Source
Other permits prerequisite to obtain ABS permit	Yes	Yes, if required: permit to access/export biological resources as prescribed under other biodiversity related laws currently enforce in Malaysia Immigration clearance Professional pass	
IRCC (Internationally Recognised Certificate of Compliance)	No		
Have ABS permit(s) been issued in the country?	Yes	As Act 795 is not enforced, no ABS permit has been issued in the Peninsular Malaysia. Sarawak: R&D permit and export permit Sabah: Access and export license	
ABS permit(s) issued by	Name of institution	Sarawak: Sarawak Biodiversity Council Sabah: Sabah Biodiversity Council	
Average timeline (from access demand to permit)	Timeline defined	Act 795: the timeline is 90 days (pending confirmation) - 90 days for commercial; 60 days for non-commercial/ potentially commercial Sarawak: 33 days Sabah: 60-90 days	Draft regulation
MAT(s) signed	No	Act 795: MAT is required for commercial /potential commercial purposes. Sabah and Sarawak: In progress	Provision 22, 23 of Act 795
MAT(s) to be signed with	Name (s) of entity	N/A	
Standard MAT clauses	No	Benefit sharing terms shall be negotiated between all parties involved. Act 795: A model benefit sharing agreement will be made available as a reference. Sarawak: MAT provisions as indicated in the regulations. (already on website)	
PIC(s) granted	Yes		

Criteria	Acquired information	Comments	Source
PIC(s) to be granted by	Name of entity	Resource providers (IPLCs) Act 795: PIC from IPLCs must be obtained to access biological resources on land to which IPLCs have a right as established by law or aTK. Sarawak: PIC granted by community leader Sabah: Representative, organization, or body in accordance with customary laws and practices, protocols, procedures of the natives and local community	Provision 23 of Act 795

6.4 Access Scenario Discussion

Tab. 4: Access Scenario Discussion Malaysia

Case	Parameter of the case	
A researcher from a national health institution in an EU member state informs the ABS authority of your country about his intention to access a specific bat species. These bats are known to be a natural reservoir for a virus, which causes non-lethal fever in humans. The researchers in the EU plan to cooperate with a domestic university in systematic capturing of the bats at various places to take blood samples. The blood analyses will be undertaken in the EU member state and should be used for creating distribution maps as basis for better understanding of the dynamics of fever outbreaks and protective measures.	**user**	health institution
	commercial or non-commercial intent	non commercial
	is the user from a party	yes
	provider in country	government
	other actors involved	university
	IPLCs involved	no
	aTK	no
	location of access	Sarawak & Perak / in situ

Under Act 795, for R&D with non-commercial purpose an applicant must apply for access permit from the relevent Competent Authority (CA) on state level. Furthermore, the research must be conducted in collaboration with a public university / public research institution / government agency, unless the CA is satisfied that:

- the applicant is a non-profit organization based or registered in Malaysia;
- local researchers are involved in the activity; and
- a program for capacity building is included in the activity.

A Statutory Declaration on the intent of the research/access duly affirmed by a Commisioner of Oath must be submitted along with other required documents when application is made with a prescribed fee.

In this situation, the researcher must obtain two permits from the Competent Authorities in Sarawak and Perak, respectively.

In addition, the researcher must also apply for other permits as prescribed in existing biodiversity related laws enforced in Malaysia as the resource of interest may be regulated; the area of access may involve protected area/national parks; and matters involving transferring of biological resources outside of Malaysia.

In case the subject of the R/D would be a lethal fever for humans, an exemption from the ABS procedure could be granted by the Minister in charge.

7 Access Procedures of Madagascar

Ms. Lolona Ramamonjisoa Ranaivoson, ABS National Focal Point, Ministry of Environment, Ecology and Forests

Ms. Rantonirina Rakotoaridera, ABS CNA Representative, Ministry of Environment, Ecology and Forests

Fig. 6: Ms. Lolona Ramamonjisoa Ranaivoson and Ms. Rantonirina Rakotoaridera

7.1 Country Presentation

Context

Madagascar is world renowned for its rich biodiversity. The country is one of the ten biodiversity hotspots and is home to about 5% of the world's biological diversity. Biodiversity plays an important role in ecological, economic and socio-cultural issues for the population.

In this context, the Government of Madagascar ratified the International Convention on Biological Diversity in 1995. Then, after signing the Nagoya Protocol in 2011, Madagascar established a national policy letter in 2012 to define the overall direction of conservation and sustainable use of the components of Malagasy biodiversity. The principles defined by the policy are based on national sovereignty, the awareness and contribution of all citizens in the issues of genetic resources and the reconciliation between conservation and development. Finally, the National ABS Policy identified three main strategies related to the legal framework, strengthening of research and an adequate institutional arrangement.

The country has subsequently ratified the Nagoya Protocol in 2014, to ensure the conservation of biological diversity and the equitable sharing of benefits arising from the use of genetic resources.

Madagascar has developed the National Biodiversity Strategy and Action Plan (NBSAP) for 2015-2025 with five strategic goals:

- Awareness of the value of biodiversity

- Reduced pressure on biodiversity
- Improving the state and valuation of biodiversity
- Strengthening benefits from biodiversity
- Knowledge management and capacity building

In its Objective 16, the NBSAP aims at the effective implementation of the Nagoya Protocol in Madagascar in accordance with national legislation and the needs of the Malagasy people.

Legal framework on ABS in Madagascar

The Government of Madagascar has adopted the Decree No. 066-2017 on 31 January 2017 regulating access and benefit sharing arising from the use of genetic resources. It entered into force on July 31, 2017 after its publication in the country's official journal.

The decree was established for a transitional period until the promulgation of the national law on ABS. The decree is composed of six chapters divided into 51 articles.

The purpose of the decree is to regulate the access and use of genetic resources and associated traditional knowledge and the fair and equitable sharing of benefits arising from their use. The decree does not apply to human genetic resources and plant genetic resources included in Annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

The decree defines the access modalities according to specific conditions such as the supply of the application file, the collection of Prior Informed Consent (PIC) of the local stakeholders concerned by the requested resource and the elaboration of the Mutually Agreed Terms (MAT) with the CNA.

The Competent National Authority (CNA), within an average of sixty days from receipt of application files and PICs, grants access. Access authorization is granted for a period of one year, renewable. However, access may not be granted if the MAT have not been concluded or if the risk of adverse impacts on biodiversity can be concluded from the access request.

The access authorization does not automatically generate the export permit, which is governed by other legal texts.

For access to genetic resources for non-commercial research purposes, the applicant must establish a letter of commitment. A change of use must be the subject of a new request and the resumption of the whole procedure.

With regard to access to genetic resources for commercial research purposes, the applicant must comply with other conditions such as:

- the delivery of a duplicate of each sample collected to a national body designated by the CNA,
- systematic information to the CNA on the progress of research,
- the interdiction of transferring resources and associated traditional knowledge to third parties and the request addressed to the CNA on intellectual property rights.

The decree describes the sharing of monetary and non-monetary benefits arising from the

use of genetic resources and / or associated traditional knowledge. Benefit sharing is a user obligation stipulated in the MAT.

Finally, the decree is mentioning that the Law No. 2013-017 on the safeguarding of the national intangible heritage governs the rights of local communities regarding traditional knowledge. These rights are in some ways offsets for efforts to conserve genetic resources.

Institutional framework

The institutional framework is composed of the Competent National Authority (CNA) within the Ministry of the Environment, Ecology and Forests, in charge of the implementation of the CBD and the Nagoya Protocol. A technical Secretariat assists the CNA and the National Correspondent (National Focal Point or NFP). An ad hoc commission composed of representatives of the different sectors concerned by the ABS mechanism (in particular the technical departments of resources management and the ministry responsible for scientific research) collaborates with the CNA and the NFP for the technical evaluation of the requests for access.

Implementation of procedures

The Annex 1 of the decree sets out the model of the access request form that the user must complete. The main information required is:

- Complete identification of the applicant;
- Identification of its partners;
- Complete identification of the genetic resources, object of the request;
- Information on the expected collection methods;
- Identification of traditional knowledge associated with the resource (if any);
- Summary of the project, with details of the intended use for the collection of resources;
- Financing of the project;
- Confidentiality on the project.

Two other papers, including the project document and the related partnership agreements, especially with a national public research institution, must accompany the application form.

The applicant delivers the entire file with the receipt of application fee payment to the CNA, which makes the control and recording in a special register. The CNA will refer to the Ad Hoc Commission who reviews the file and provides an opinion. Decision on the application from CNA would comply with the opinion of the Ad Hoc Commission, in case of a **commercial access request**. In the application processing process, the CNA directs the applicant to acquire PICs from the various stakeholders involved in the resource. The CNA also initiates with the applicant the benefit-sharing negotiation arising from the future use of the resource. A non-exhaustive list of monetary and non-monetary benefits is annexed to the decree.

After the acquisition of the PICs and at the end of the negotiations, the MAT are established in the form of a contract between the applicant and the CNA, and the access permit is issued.

Applicant for a **non-commercial access request** has to provide a letter of commitment attesting that he/she agrees to inform the CNA in case of change and make a new access request.

Implementation experiences

Madagascar is in the process of learning about the implementation of the Nagoya Protocol with the recent adoption of the decree. Thus, at present, the implementation is limited to the extension of regulation to the many users undertaking research and development activities on genetic resources from the country. Some of these entities have already had previous activities in this area, collaborating with local operators responsible for the collection and export of resources and others are in prospect of investing in the field.

Previously, the collection of genetic resources was governed by decree n°2915/87 on the exploitation of forests accessory products and the regional directorates of the Ministry of the Environment, Ecology and Forests are responsible for issuing collection authorizations and export permits. With the advent of the Nagoya Protocol in Madagascar, these practices are undergoing change to better regulate access and share benefits from their use. Thus, the request for transparent and clear information on the use (domestic and foreign) of resources constitutes an important lever for the effective implementation of the ABS mechanism in Madagascar.

The entities representing the CNA in the Ministry of the Environment, Ecology and Forests are also in charge of receiving requests for research authorizations and issuing permits. At present, it is therefore imperative to discern the aims of research based on genetic resources (commercial or non-commercial) in order to ensure compliance with the Nagoya Protocol.

In bioprospecting, Madagascar implemented through ICBG (International Cooperation Biodiversity Group) a program for 15 years from 1998 to 2013 with a consortium of partners as Virginia Polytechnic Institute and State University in Blacksburg, three national research centers, two international NGO operating in the country, Eisai Pharmaceutical Research Institute, and Dow Agrosciences. It was started before the signature of Nagoya Protocol by Madagascar in September 2011. Even with the ICBG program implemented in Madagascar not having a formal policy on bioprospecting and benefit sharing, this is considered as a first application in the the spirit of ABS under the CBD. Upfront compensation funding is provided by the industry partners to the ICBG. This is then split in a way that 50% of the funding goes to the national centres for specific infrastructure enhancement and purchase of research equipment, plus 50% to community-based projects around the bioprospecting collection sites. All parties involved committed to use these funds only for research, research training, research infrastructure, biodiversity conservation, or economic development in Madagascar, in consultation with local stakeholders. There were a number of non-monetary benefits arising from the different aspects of the project. However, without any framing regulations for the project, various aspects were dysfunctional in its implementation. This includes, for example, direct access to resources by foreign researchers, the granting of benefits to different stakeholders without negotiation on the equitability and the content of the contract that ignored the sovereignty of the Malagasy State, as it should be. Many lessons are learned from this project for the implementation of a national bioprospecting program envisaged in the implementation of the Nagoya Protocol in Madagascar.

Outlook

Madagascar's perspectives through the Ministry of the Environment, Ecology and Forests for the ABS mechanism are:

- Elaboration of the implementing texts of the decree
- Consistency of existing legal texts on the biological resources / genetic resources with the ABS decree
- Update of the national policy on ABS
- Development of the national strategy on ABS
- Drafting of a national law on ABS
- Strengthening inter-sectoral coordination on ABS
- Strengthening communication, awareness and capacity building on ABS
- Inventory of genetic resources, uses, markets, associated traditional knowledge, etc.
- Development and implementation of a bioprospecting national program
- Establishment of the necessary devices on traditional knowledge
- Support for pilot projects on ABS

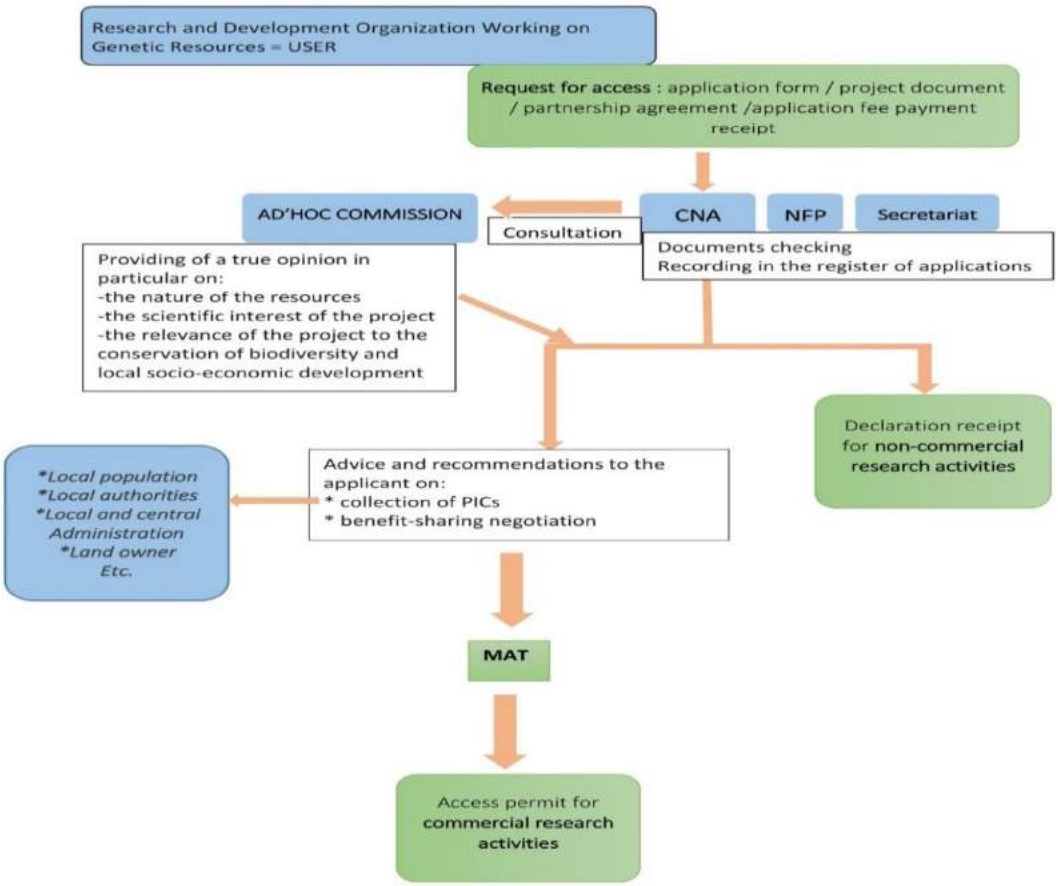


Fig. 7: Flow Chart Madagascar

7.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- All GR accessed in Madagascar fall under the Malagasy legislation. It makes no difference whether Madagascar is the country of origin of the GR. Madagascar thus has the same position as the EU which considers that the GR is from the place where it was accessed.
- Before access is being granted in Madagascar, the user has to mention his intention. Use is only allowed for one specific action (one use per permit). The need to renegotiate in case of change of intent is also mentioned in the permit. But since this is difficult to monitor, the compliance mechanisms in user countries, such as the one in the EU, are so important.
- Madagascar is a country that is very rich in GR and aTK. Efforts must be undertaken to document TK.
- The Malagasy Industrial Property Office (OMAPI) plays a key role in the ABS process in Madagascar. Even if patents are filed in the EU, OMAPI needs to receive relevant information.
- Madagascar aims to ensure consistency between the existing legal texts on the biological resources / GR and the ABS decree.

7.3 Access Profile

Tab. 5: Access Profile Madagascar

Criteria	Acquired information	Comments	Sourcee
Party Nagoya Protocol	Yes	Ratification in July 2014	
Signatory	Yes	Signatory in September 2011	
NFP (National Focal Point)	Ms. Lolona Ramamonjisoa Ranaivoson		
Contact NFP	lolona.ramamonjisoa@gmail.com +261 34 39 818 16		
CNA (Competent National Authority)	Yes	Act N°19831-2018- MEEF on August 21th, 2018	
Contact CNA	rakotoaride-ra@yahoo.fr +261 34 05 621 45	Director of Protected Area System, having in charge the Biodiversity Conservation, Ministry of Environment, Ecology and Forests – CBD NFP	
CNA Deputy	Yes	Chief of Biodiversity Conservation Service, Ministry of Environment, Ecology and Forests	
Contact CNA Deputy	volah2001@yahoo.fr +261 34 72 540 25		

Criteria	Acquired information	Comments	Sourcee
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	No	It should be designated in the future.	
ABS law	Yes	Decree n°2017-066 of January 31st, 2017	
Specific access regulation	Yes	Modalities of access are specified in Chapter 2 / Section 1 of the Decree. The application form is presented in Annex 1 of the Decree.	
Specific access procedures (law or any defined process) for non-commercial use	Yes	Modalities of access in Chapter 2 / Section 1 / Paragraphs 1 & 2	
English translation for users	No	English translation is envisaged.	
Visualization of ABS procedure	No	Publication of ABS Decree in the ABS-CH	
Information on access procedure / regulations accessible through weblink	Yes	It is presented in ABS-CH.	
Access demand form	Yes	It is presented in ABS-CH. It is provided by e-mail to applicants who are asking for.	
Specific access demand form for non-commercial purposes	No	The form is the same for non-commercial and commercial purposes.	
Online application system	No	It could be envisaged in the future.	
Compulsory documents for access demand application	Yes	*Application form *R&D Project document *Collaboration Agreement between the Applicant and a national public research institution	

Criteria	Acquired information	Comments	Sourcee
Submission of access application at	No information	Different applicants are on phase of learning and understanding the new regulation should be submitted to CNA	
Access fees	No information	To be fixed in the future	
Other permits prerequisite to obtain ABS permit	No		
IRCC (Internationally Recognised Certificate of Compliance)	No information	It would be established in the future.	
Have ABS permit(s) been issued in the country?	No	However, there are already requests which are studied in compliance with the national ABS regulation. Applicants are recommended to comply with procedure with the regulation, such as a letter of commitment of use for non-commercial research.	
ABS permit(s) issued by	Name of institution	CNA	
Average timeline (from access demand to permit)	Timeline defined	60 days	
MAT(s) signed	No		
MAT(s) to be signed with	Name (s) of entity	CNA and user	
Standard MAT clauses	Yes	Madagascar should use the model suggested in AU practice guidelines	
PIC(s) granted	No		
PIC(s) to be granted by	Name (s) of entity	Needs to be defined in implementing texts (local communities, stakeholders in general)	

7.4 Access Scenario Discussion

Tab. 6: Access Scenario Discussion Madagascar

Case	Parameter of the case	
A researcher of a domestic university informs the ABS authority of your country about his intention to travel to an EU member state and take some snakes and venom from a collection with him. The snakes are common in your country and were caught on the ground of the university. He will undertake analyses on the venom, in cooperation with a university in an EU member state. This university will check the results on its potential to be patented.	**user**	European university
	commercial or non-commercial intent	commercial
	is the user from a party	yes
	provider in country	Madagascan university
	other actors involved	none
	IPLCs involved	no
	aTK	no
	location of access	ground of university & collection / in situ & ex situ

The head of the research center in the EU, where the Malagasy researcher will provide the snake and venom samples, should submit the application for access to the CNA. The file will include the application form (following the model in Annex 1 of the national regulation in the ABS decree n° 066-2017), the project document detailing the objectives and the modalities of research envisaged and the partnership agreement with the local University.

The CNA will deal with the case with the support of an Ad'hoc Commission that will include, among others, a representative of the Ministry of Scientific Research, the Ministry of Health, the Malagasy Association of Traditional Medicine Practitioners and the Malagasy Office of Intellectual Property.

The commercial purpose of the proposed research would require the sharing of benefits by the research center within the EU with the local University, the Environment Ministry, the Ministry of Health and eventually the Malagasy Association of Traditional Medicine Practitioners in case traditional knowledge on their part is exploited by the research carried out.

By this aspect, the applicant must acquire the PICs from these different stakeholders.

Taking into account the different PICs and considering the specific aspects related to the possible patenting modalities of the research results, the CNA and the user jointly negotiate and develop the MAT.

The CNA would issue the access permit in compliance with the Ad'hoc Commission's statement.

8 Access Procedures of the Republic of Seychelles

Mr. Denis Matatiken, ABS National Focal Point, Ministry of Environment, Energy and Climate Change

Ms. Marie-May Muzungaile, Director General, Biodiversity Conservation and Management Division, Ministry of Environment, Energy and Climate Change

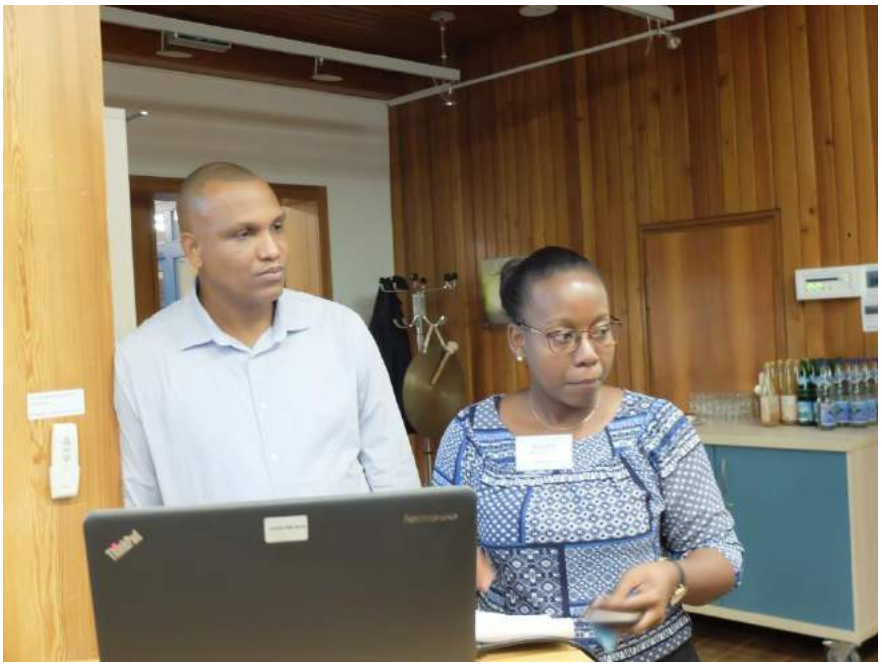


Fig. 8: Mr. Denis Matatiken and Ms. Marie-May Muzungaile

8.1 Country Presentation

Introduction

The Seychelles is a group of 115 islands located between 4-5 degrees south of the Equator. The islands are of granitic and oceanic origin. The granitic islands of the Seychelles are the only mid oceanic island of continental origin, believed to be fragments of Gondwanaland. The islands have a total land area of 454 square kilometres spread in an exclusive economic zone of 1.3 million square kilometres of ocean.

Due to its small size, the Seychelles is considered a Small Island Developing State and also a large oceanic state. With a population of 95,000 people, the economy of the country is mostly dependent on tourism and fisheries which are considered the two main pillars of our economy. Given our dependence on the environment for the country's socio-economic development, Government recognises the need to protect its environment that is part of its natural heritage.

The biodiversity of the Seychelles is unique with high endemism and as a result, it is considered a biodiversity hotspot. Many species are only found growing naturally in only that part of the world. The Seychelles Government recognises the value and also the need to protect its natural heritage. It has designated almost 50% of its terrestrial territory as legally protected and has also given its commitment to increase the marine protected areas from 1% to 30% by 2020.

Seychelles is a leader in environment protection and has shown its commitment globally. It was the second country to sign the Convention on Biodiversity in 1992 and later ratified it in 1993. It was also the 4th country to sign the Nagoya Protocol in 2012 and ratified it in 2014.

Despite these strategic moves, the Seychelles has been slow to domesticate the provision and obligation of the multilateral agreements, of which some are legally binding. Government recognises the need to adhere to its national obligations under the CBD and the Nagoya Protocol. Article 64 of the Seychelles Constitution also makes provision for Government to domesticate any agreement it has ratified. Article 38 (b) gives the Government the right to ensure that the genetic resources are used sustainably to ensure a sustainable socio-economic development of Seychelles. It has responded to some of these obligations by prioritising them under various country's policies such as NBSAP and the Seychelles Sustainable Development Strategy (SSDS).

Legal framework for ABS implementation

Seychelles does not presently have a legislative framework to domesticate and regulate access to genetic resources and associated traditional knowledge. A draft Bill for access to genetic resource was developed in 2005 with the financial and technical support of IPGRI. The purpose of the Bill was to be used as a tool to implement the Plant Treaty which it ratified in 2006. The Bill never made it to parliament. The process was facilitated by local experts with the assistance of international experts.

Almost 13 years later, the Government has developed a Policy framework pertaining to Access and benefit sharing. The intention is to have a framework to domesticate the Nagoya protocol. The Policy also makes provision for the development of a new law that takes into consideration the existing gaps in the interim measures.

Seychelles requires a new legislation to regulate access to and also benefit sharing arising from the use of genetic resources and associated traditional knowledge. There is presently a demand for genetic resources mostly for non-commercial use. There is presently more demand for bio-prospecting. The Competent National Authority processes about 30 applications every year.

Institutional framework for ABS implementation

The Seychelles has designated a National Focal Point as articulated under Article 13 of NP. The Focal Point is based in the office of the Ministry of Energy and Climate change. The Ministry is also the competent National Authority which grants Prior Inform Consent and also signed Material Transfer agreement for access to any genetic resources.

Most of the applications received are for non-commercial purposes, mostly for research. The Competent National Authority is also working with other agencies to process all access applications.

Several institutions are currently working as lead agencies implementing the functions of CNAs as defined by the Nagoya Protocol: The Seychelles Bureau of Standards, which processes the applications; MEECC, which approves all applications and the Biodiversity Conservation Section within MEECC, which issues the MTAs.

Steps to access the country's genetic resources (Steps)

Although there is no legal framework pertaining to access to the country's genetic resources and traditional knowledge, the Seychelles has interim measures in place. Such

measures however, only apply to access to genetic resources for research purposes only.

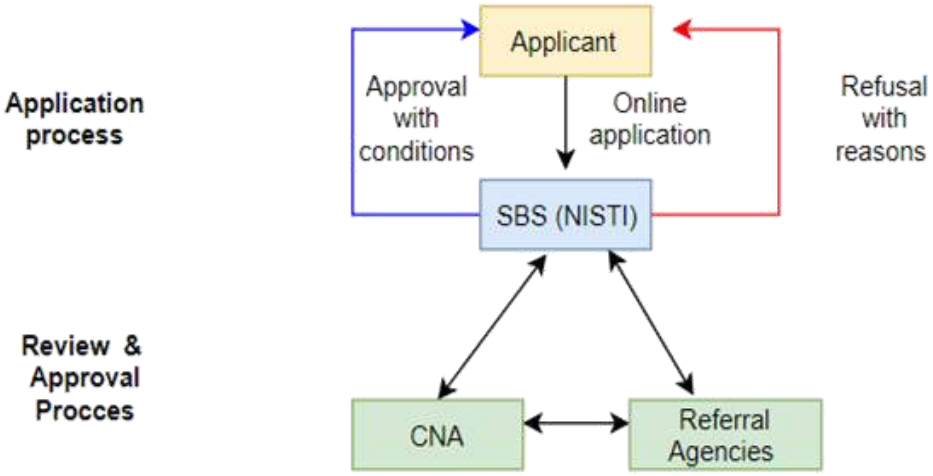


Fig. 9: Flow Chart Republic of Seychelles

Any person/institution can apply for access to the country's genetic resource mainly for research purpose. The research application form can be obtained from the Seychelles Bureau of Standards (SBS) and may also be downloaded from the Research Application Form Download Link on the SBS website at http://www.sbs.sc/index.php/2013-09-27-07-29-40/application-form. Applicants are required to submit a comprehensive research proposal with their application.

Once the SBS receives the application form, it sends out an acknowledgement to the applicant. The application form and research proposal is then forwarded to the competent National Authority (MEECC) to be appraised together with other partners such as the National Biosecurity Agency, government ministries and departments and environmental non-governmental organisations. Should there be no adverse comments or an outright refusal, SBS issues a Research Permit giving researchers authorisation to conduct research within the Seychelles. In that Research permit (PIC process), the applicant is then provided with the conditions of access. Should there be an outright refusal, SBS inform the applicant accordingly.

Once the applicant is ready to access the genetic resources, it contacts the competent National Authority. The CNA then issues the applicant with specific guidelines and conditions for access (e.g location to access the genetic resource).

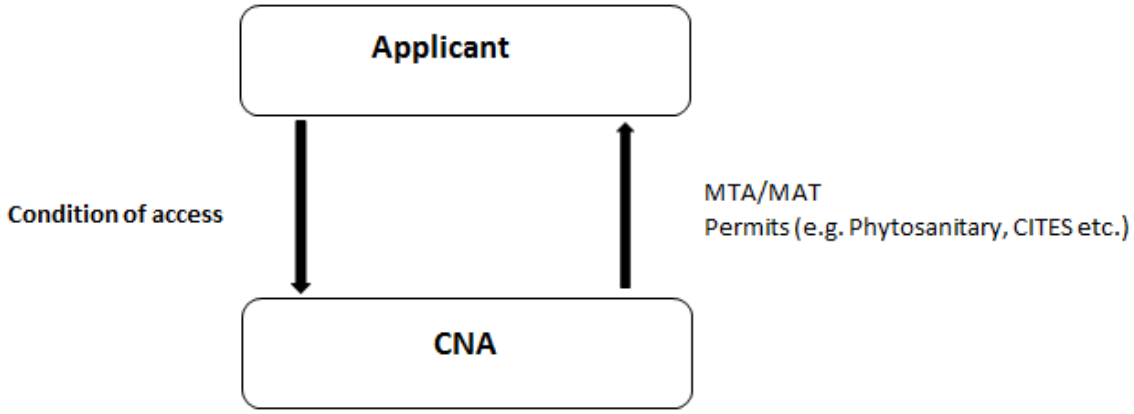


Fig. 10: Post approval

Upon collection and satisfaction of the CNA, the applicant then signs an MTA with the Director of Biodiversity Conservation Section within the MEECC. The MTA states conditions for use of the genetic resource as well as the reporting requirements of the applicant. There is also a clause to include benefit sharing too. The applicant has to honour those specific conditions stipulated under the MTA.

This process is the interim measure in place pending the completion of the new ABS laws that will provide the processes and also conditions for the applicant. At present the CNA is in the process of revising the MTA provisions in order to comply with Article 19 of the Nagoya Protocol regarding the development and use of MATs in particular to provide for legal recourse at the international level in cases of infringement of the provisions of the contract. To go further, the Seychelles is also considering issuing contract with applicants as stipulated by the new ABS policy. Moreover, provision also is being made for an applicant to appeal in the event that the applicant received outright refusal.

Weaknesses with interim measures

The Seychelles recognizes that there are presently some weaknesses with the interim measures. Such measure does not necessarily satisfy the obligations under the convention. Some of these include:

- There are only measures to regulate access for non-commercial but not for commercial use of the genetic resource;
- The interim measures do not address access and benefit sharing related to TK
- No permits being posted on the clearing house mechanism
- No checkpoints established

The Seychelles is presently working to address these issues by developing a new Policy on Access and Benefit Sharing. The vision articulated in the new policy is "To achieve the optimal, fair and equitable, social, economic and environmental benefits through the conservation and sustainable use of biological natural resources'. The policy was developed in consultation of all stakeholders. The Policy is awaiting approval from the Cabinet of Ministers.

The Policy makes provision for the development of a new ABS legislation. The new legislation will provide legal guidance on access to the GR and TK (PICs, Mutually Agreed Terms

– MATs), establishment of the institutional arrangements, mechanism for benefit sharing. It is good to note that the new Bill will take into consideration the Nagoya Protocol and IT-PGRFA into context.

Conclusion

The Seychelles presently have measures to implement both the Nagoya Protocol and also IPGRFA. Despite the measures are the minimal requirements of the Nagoya Protocol, the Seychelles is trying to fulfill its obligation. Works are already in progress to develop a national Policy for access to the country's GR and TK and also mechanism for benefit sharing arrangement. The new Policy will also pave the way for the development of a new ABS legislation.

8.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- Until the new legislation is in force, the Seychelles is not issuing any permits. Currently MTAs are being used (approx. 30 per year).
- So far, the Seychelles is mainly being approached by researchers for non-commercial research purposes. A weakness of the interim measures of the Seychelles is that they only regulate access for non-commercial purposes. All commercial access demands are currently not being further processed.
- The Seychelles has created a one-stop-shop approach for accessing GR / aTK.
- If traditional knowledge has already become common knowledge and is thus in the public domain, it does not trigger ABS. But the difficulty is to draw the line – when has something become common knowledge?
- The issue of benefit-sharing is a new area for the Seychelles and raises many questions. There is a high demand for capacity-building on ABS contracts in general and benefit-sharing modalities in particular.
- It is not the role of the CNAs in user states to enforce the access obligations of the applicant. This was clarified at the 1st Vilm ABS Dialogue in 2017.
- The CNA in the user country is not a Party to the contract signed between the user and provider.
- The need for further exchange on the topic of benefit-sharing has been established at a workshop held by the European Commission in November 2017 in Brussels.
- It is very difficult to find information on ABS contracts and benefit-sharing. The BfN is planning to collect information on ABS cases and benefits that have been shared. The annual UEBT conference in Paris provides a good opportunity to learn more about ABS cases.

8.3 Access Profile

Tab. 7: Access Profile Republic of Seychelles

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	Yes	2014	ABS-CHM
Signatory	Yes	April 2012	ABS-CHM
NFP (National Focal Point)	Mr. Denis Matatiken		ABS-CHM
Contact NFP	boga@seychelles.net dmattiken@env.gov.sc denis_matatiken@hotmail.com +248 4610740 +248 2723417		ABS-CHM
CNA (Competent National Authority)	Yes	Ministry of Environment, Energy & Climate Change	ABS-CHM
Contact CNA	P.O Box 445, Victoria Mahe, Seychelles m.mjeremiemuzungaile@env.gov.sc +248 4670500	Ministry of Environment, Energy & Climate Change	
CNA Deputy	No		
Contact CNA Deputy	Telephone Email	N/A	
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	No	ILCs does not apply in the Seychelles.	
ABS law	No	A draft law exists but was never gazetted. A new legislation is being developed in parallel to an ABS Policy. This process is being facilitated by the Global ABS project with funding from GEF.	
Specific access regulation	No	Administrative procedure for access exists in the absence of an ABS Law. All research application has to go through SBS (This may change following the development and implementation of the new ABS Policy).	

Criteria	Acquired information	Comments	Source
Specific access procedures (law or any defined process) for non-commercial use	Yes	For all requests, currently only for non-commercial use, the applicant needs to download and complete an SBS research application form (http://www.sbs.sc). The applicant also needs to submit a detailed project proposal, and supporting documents to accompany the application.	
English translation for users	Yes	Already in English	
Visualization of ABS procedure	No	In process	
Information on access procedure / regulations accessible through web-link	No	.	
Access demand form	Yes	Available at SBS website (http://www.sbs.sc)	
Specific access demand form for non-commercial purposes	Yes	Available for download at the SBS website	
Online application system	No	The application form is available online but has to be downloaded, completed and then emailed or hardcopy submission.	
Compulsory documents for access demand application	Yes	A detailed project proposal also needs to be submitted with application form.	
Submission of access application at	Name of institution	The Seychelles Bureau of Standards	
Access fees	No	Access fees should come in the future.	
Other permits prerequisite to obtain ABS permit	Yes	A research permit from SBS is a requirement.	

Criteria	Acquired information	Comments	Source
IRCC (Internationally Recognised Certificate of Compliance)	No	Not yet	
Have ABS permit(s) been issued in the country?	Yes	Many permits have been issued through MTA. Most of these have been for the non-commercial use of biodiversity (approximately 30 issued per year).	
ABS permit(s) issued by	Name of institution	Biodiversity Conservation and Management Division Department of Environment	
Average timeline (from access demand to permit)	Timeline defined	3 to 4 weeks for a research permit (Depending on queries from stakeholders and partners) (In reality, it takes about 1-3 months until requests can be permitted, especially if users do not give every information correctly)	
MAT(s) signed	Yes	In the form of Material Transfer Agreement (MTA)	
MAT(s) to be signed with	Name (s) of entity	Applicants and the Director General for Biodiversity Conservation and Management Division (MEECC)	
Standard MAT clauses	Yes		
PIC(s) granted	Yes	PIC is granted during the application process.	
PIC(s) to be granted by	Name of entity	MEECC through the Seychelles Bureau of Standards	

8.4 **Access Scenario Discussion**

Tab. 8: Access Scenario Discussion Republic of Seychelles

Case	**Parameter of the case**	
A food company from an EU member state informs the ABS authority of your country about its intentions to harvest seaweed at a certain place of the coast, which is traditionally used as health food in many countries. The company will undertake R&D on the biochemical properties of the seaweeds back in the EU member state and plans to develop new food applications for the seaweed.	**User**	food company
	commercial or non-commercial intent	commercial
	is the user from a party	yes
	provider in country	government
	other actors involved	none
	IPLCs involved	no
	aTK	yes
	location of access	at the coast / in situ

Presently the Seychelles do not have or makes provision for commercial use of its genetic resources pending the finalising of its legislation. Consideration will be given of what will happen under such a scenario.

The applicant will first have to complete an application form (Available from the SBS website http://www.sbs.sc/index.php/2013-09-27-07-29-40/application-form). The applicant will need to provide details on the GR he is trying to access, use, amount etc. The application will then be reviewed by various local partners. If it is not approved the applicant will be informed accordingly.

If consideration is being given to the application, the CNA and also the Ministry for Environment may request further information given that the materials will be collected in situ. The applicant may be required to undertake a feasibility study and also an EIA on the impact of the collection on the other species such as hebivourous fish and how that may also have an impact on the species.

It would also be good if the applicant can also state where TK was obtained and whether permission was granted.

If the application for access and collection is approved, conditions will be issued to the applicants. An agreement with benefit sharing modalities will apply. For example, Seychelles may ask the Company to engage the locals in the collection or may even advise the company to set its base here in the Seychelles so that it can create employment to the people of Seychelles. But these conditions will only be as a result of negotiation.

9 Access Procedures of Ecuador

Mr. Ricardo Andrade, GR Analyst, National Directorate of Biodiversity, Ministry of the Environment

Mr. Pablo Cueva, Secretariat of Higher Education, Science, Technology and Innovation (SENESCYT)

Fig. 11: Mr. Ricardo Andrade and Mr. Pablo Cueva

9.1 Country Presentation

Introduction

Ecuador is a country that is located in South America between Colombia and Peru. It is considered one of the 17 most megadiverse countries in the world. Some of the relevant data of the country can be seen in the following radial graph (Fig. 12- http://gapframe.org/by-region/south-america/ecuador/):

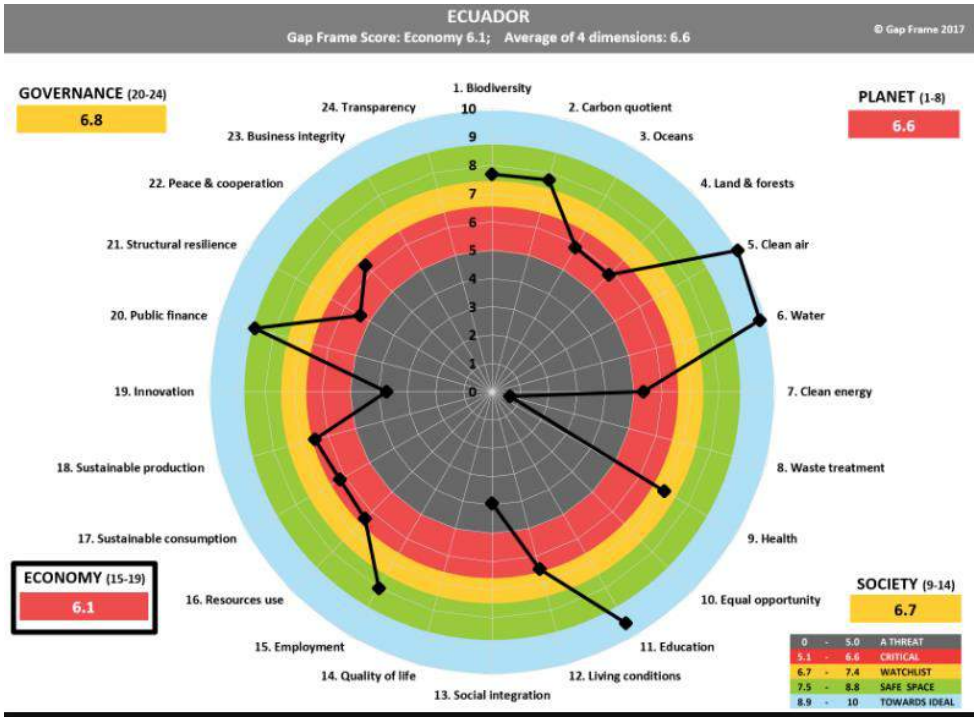


Fig. 12: Radial chart on indicators of Ecuador

Indicators with values over 10 points are observed: biodiversity (7.7); carbon ratio (7.7); lands and forests (5.8); water (9.8), clean energy (5.3) among others. Regarding the conservation areas in Ecuador, there are currently 56 protected areas that correspond to 20% of the countries' surface, comprising approximately 5 million hectares.

Legal framework

The Constitution of the Republic of Ecuador (Official Gazette No. 449 of October 20th, 2008), indicates that biodiversity and genetic heritage are part of the strategic sectors, over which the State reserves the right of administration, regulation, control and management in accordance with the principles of environmental sustainability, precaution, prevention and efficiency. It prohibits appropriation of GR containingbiological diversity and agrobiodiversity.

Ecuador has been a member of the CBD since 1995. It ratified the Nagoya Protocol in August 2017 (Official Register No. 533, of September 13th, 2011), which is part of the most important block of international law related to the ABS system.

Ecuador is a member of the Andean Community of Nations and submits to the provisions of the Andean regime:

Andean Decision 391 establishes the Common Regime of Access to GR. This supranational norm provides important elements to establish an ABS regime in Ecuador, such as: access procedure, access contracts, limitations, infractions and sanctions, functions of CNAs, creation of the Andean Committee of GR.

The Organic Code of Environment (COA) ratifies the constitutional principle of sovereignty of the State over GR and makes a separation between the rights over biological material and rights over genetic material and declares its strategic nature.

This regime has been deepened with the issuance of the Organic Code of the Social Economy of Knowledge, Creativity and Innovation COESCCI in 2016.

Article 25 of the Regulation to COESCCI states that access permits for research purposes to GR and their derivatives for research or commercial purposes, as well as import permits for living organisms, specimens from scientific collections aimed at the development of research processes will be processed through a single window for research for biodiversity in which the governing entity of the National System of Science, Technology, Innovation and Ancestral Knowledge will inter-operate, in coordination with the Public Institute of Scientific Research on the Biodiversity, the National Environmental Authority, the customs authority and other institutions whose involvement is necessary to achieve the purposes established by the regulation.

In compliance with Article 25, Ecuador has developed, in coordination with the institutions involved in the process, a management model that identifies different access authorization processes, namely:

1. It is a model based on the simplification and coordination of procedures.
2. It is articulated with the implemented system of Registration and Accreditation in force in the country.
3. Identify three different authorization processes: the first corresponds to research permits that do not imply bioprospecting and industrial application, the second corresponds to an access contract for research that develops bioprospecting and the

third consists of an access contract for commercial purposes, detailed in (Fig. 13):

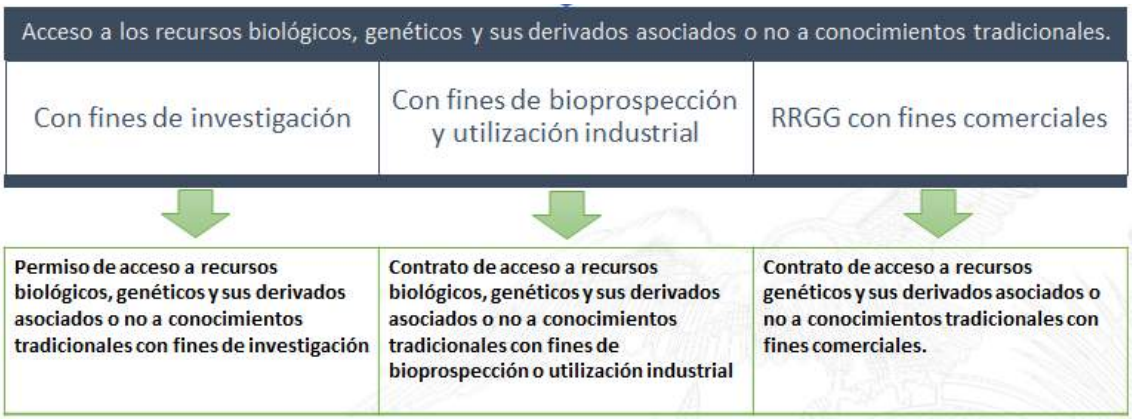


Fig. 13: Proposition for a new management model in Ecuador 2018

4. It incorporates the mobilization permits and the import and export permits as an integral part of the access authorization, substantially simplifying the procedures required for the development of the investigation.
5. With the exception of the access contract for commercial purposes, the other permits are treated as accession models, which will also simplify the process.

Finally, it proposes a virtual monitoring and monitoring system, through reports that allow SENESCYT to comply with the annual monitoring on the state of GR in the country and to link our authorizations issued in accordance with the Right to Access Information Exchange Center and Benefit Sharing of the Nagoya Protocol.

Access procedure

Access to scientific research is carried out in two ways as shown in the following flow diagram as detailed in Fig. 14:

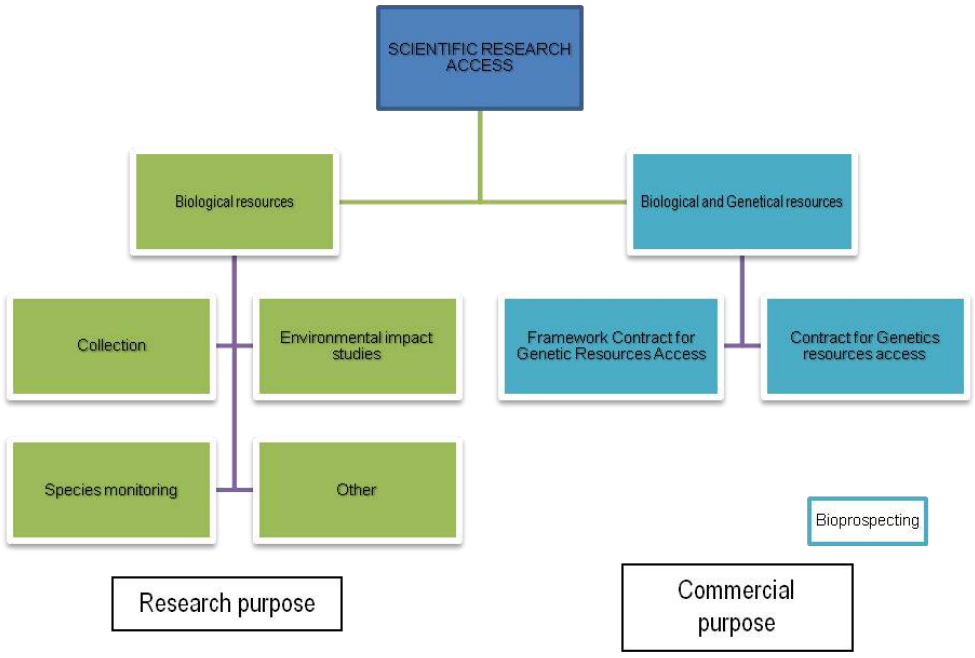


Fig. 14: Flow Chart about kind of scientific research access in Ecuador

When you are going to make access only to the biological resource it can be for collection, environmental impact studies, species monitoring.

On the other hand, when it comes to GR, it is done through a framework contract for access to GR (for research purposes) or a contract for access to GR (for commercial or bio-prospecting purposes).

The components of the application for the framework contract for access to GR are the following:

- Forms
- Information about the institution and technical support
- Information about GR (number of samples, type of samples), collection sites, and whether GR are associated or not with TK.

The information requested for the projects / programs is the following:

Title, objectives (general and specific), justification, methodology, results, duration of the investigation.

For the application process for access to GR in Ecuador, the steps detailed in Fig.15 should be carried out:

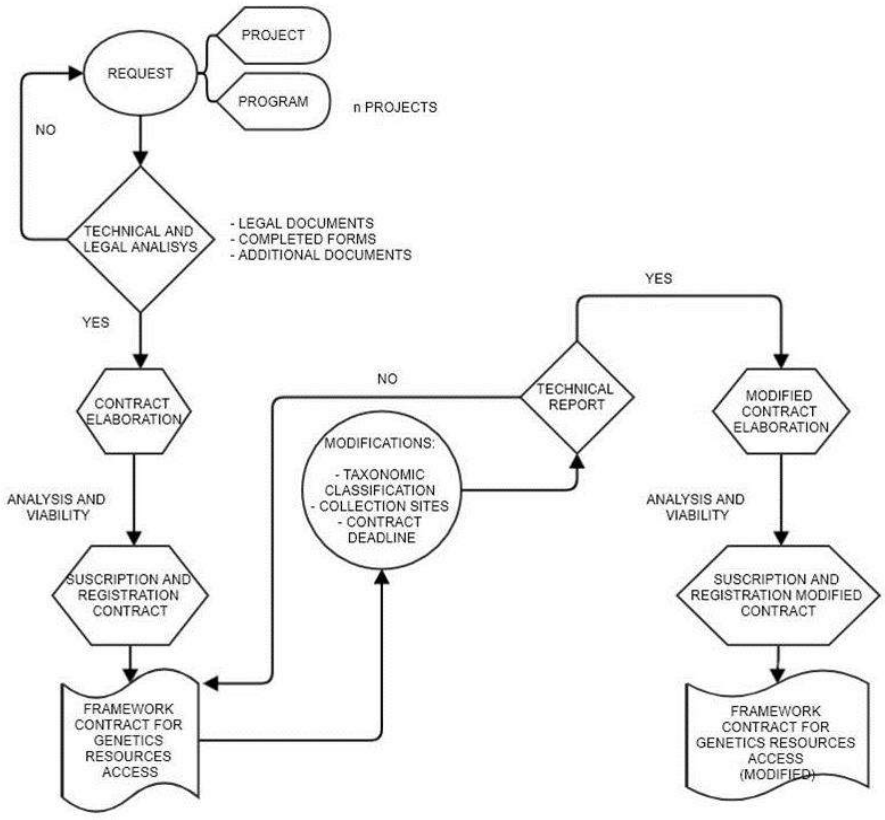


Fig. 15: Flow Chart Ecuador

The framework contract allows authorized access as well as the collection of samples.

There is another requirement within the country that is the mobilization guide, which is a document that authorizes the mobilization and possession of biodiversity material and may

be required at some point on the roads of Ecuador.

On the other hand, if the investigation requires it, the framework contract together with the MTA are necessary documents for the export of samples to send material coming from biodiversity abroad.

When talking about the statistics that have been generated from 2014 to the present, we have the following information:

Approximately 81 contracts have been signed and are in the process of being reviewed and 13 are under review as part of internal processes within the Ministry of Environment.

There are currently 25 investigations in the "program" modality and 65 in the "project" modality with a total of 163 scientific research studies.

From around 32 national support institutions (universities, research centers) the tendency is to carry out projects instead of programs. Although the programs offer the advantage of being made up of several projects that share the same line of research and allow to enter projects during the useful life of the program.

Of these entities, 67% are private, 26% public, and only 7% are non-governmental organizations (NGO).

Most of the types of resources that Ecuador investigates are: 61% animal resources, 25% in plant resources, 12% in microorganisms and 2% in metagenomics (considering that many resources are investigated at the same time).

The type of samples sent are mostly (74%) of biological samples (hair, nails, feces, blood, semen, etc.), entire specimen (17%), (7%) DNA and 2% sediments.

Researchers in Ecuador maintain scientific collaboration with many countries in Latin America, Europe, Asia and Oceania. With universities recognized worldwide for their constant work in research and conservation of biodiversity such as: Cambridge University, Memorial University of Newfoundland, James Cook University, Stanford University, Smithsonian Institution, Technische Universität Braunschweig, Wageningen University.

Experiences in Ecuador

Two projects are currently under execution, with the support of the GEF, the UNDP, Ministry of Environment, the United Nations Volunteers Program and the IKIAM Amazon State University: ABS Global Project and the amphibian GR project (PARG).

The PARG project focuses on three components: 1) Emerging actions for conservation purposes; 2) Bioprospecting in amphibian skins and 3) Institutional strengthening.

On the other hand, as a strategy to implement the Nagoya Protocol, Ecuador has two biocommunitarian protocols. The first example was an initiative where an added value was added to palo santo (Bursera graveolens), which allowed the community to be the driving force behind this initiative.

Likewise, the biocommunity project of the Al'Kofan indigenous community, which was designed to promote the management and commercialization of products derived from the biodiversity found in the local territory.

Finally, an interesting document on the economic assessment about GR is placed before the invited countries. A consultancy that was developed with the support of the German

Cooperation GIZ, which includes an economic exercise on the perspecting that can be generated by generating basic research and potential scenarios that are considered if an applied research would be reached.

9.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- PIC only applies in Ecuador if TK is involved. If biological resources are accessed without TK, PIC is not needed even if it is accessed on the lands of local communities because then the resource belongs to the government.
- A publishing authority needs to be designated in order to publish information on the ABS-CH.
- The use of different terminology is a challenge. It is important that provider countries upload relevant information on the ABS-CH in order to help users navigate the respective ABS system.
- According to the Constitution of Ecuador, benefits are to be shared with the government when a commercial contract is concluded. Efforts are currently made to reduce this percentage to 7%.
- There is no legal framework for access to GR / aTK for commercial purposes yet.
- In Ecuador a local counterpart is a prerequisite for foreigners wishing to undertake on GR and or aTK.

9.3 Access Profile

Tab. 9: Access Profile Ecuador

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	Yes		
Signatory	Yes	Date of subscription: 01/04/2011 Date of ratification: 20/09/2017	http://bch.cbd.int/protocol/parties/
NFP (National Focal Point)	Mrs. Pamela Rocha Director of Environmental and Sustainable Development Affairs, Ministry of Foreign Affairs and Human Mobility of Ecuador		

Criteria	Acquired information	Comments	Source
Contact NFP	pro-cha@cancilleria.gob.ec dads@cancilleria.gob.ec mvaldivieso@cancilleria.gob.ec +593 2 299 3200 ext 11551		
CNA (Competent National Authority)	Yes		
Contact CNA	Ricardo Andrade ricardo.andrade@ambiente.gob.ec Carolina Zambrano czambrano@senescyt.gob.ec		
CNA Deputy	Yes		
Contact CNA Deputy	alfonso.rojas@ambiente.gob.ec internacional@ambiente.gob.ec +593 2 3987600 ext 1422		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	Yes	The Secretariat of Higher Education, Science, Technology and Innovation (SENESCYT)- Undersecretariat of Scientific Research; and the National Service of Intellectual Property (SENADI) - Department of Traditional Knowledge	
ABS law	Yes	Common Regime on Access to GR: Decision N° 391 of the Andean Community (CAN)	
Specific access regulation	Yes	Executive Decree N° 905 of the Official Record, Suplement 553 from October 11th, 2011 Ministerial Agreement N° 034 on the norms and procedure for the subscription of framework contracts for access to GR, from February 4, 2015	

Criteria	Acquired information	Comments	Source
Specific access procedures (law or any defined process) for non-commercial use	Yes	Decision N° 391 of the Andean Community (CAN), July 2nd, 1996 Ministerial Agreement N° 034 on the norms and procedures for the subscription of framework contracts for access to GR, February 4th, 2015	
English translation for users	No		
Visualization of ABS procedure	No	In process	
Information on access procedure / regulations accessible through web-link	No	ABS-CH Ecuador	https://absch.cbd.int/countries/EC
Access demand form	Yes	A set of forms: Framework contract form for genetics resources suscription (B1.1) CV of theTechnician/Expert (B.1.6) CV of the experts from the Work Group (B.1.7) Draft programmes (B.1.8) MTA	
Specific access demand form for non-commercial purposes	No information		
Online application system	No	The scientific research platform is under construction according the Art. 25 from Organic Code on Social Economy of Knowledge, Creativity and Innovations (COESCCI).	

Criteria	Acquired information	Comments	Source
Compulsory documents for access demand application	Yes	If any institution needs to access GR, it has to present an application, attaching the following documents: Appointment certificate of the Principal/Chief from the national institution of support (universities or research centres) that is applying. Document about institution creation Research proposal form (project / programme), according the format established by the National Environmental Authority	
Submission of access application at	Name of institution	Ministry of Environment At the moment, the Ministry of Environment is receiving all applications for access to GR. Although, the Secretariat of Higher Education, Science, Technology and Innovation (SENESCYT) is currently working on a scientific research platform, which among other things, will collect applications for access to GR. This platform is expected to be working in the medium/long term. In the cases of accessing GR for commercial purposes, this process is managed by the National Institute of Biodiversity (INABIO). There is no normative/ legal framework for commercial purposes (treated like non-commercial for now but will be changed in the future when there is a normative)	
Access fees	No for GR, but yes for biological resources under certain circumstances.	If a biological resource (the plant or animal itself) or a part of it is accessed (e.g. for taxonomic study, sample for collection, photo, film, etc.), a fee of approx. 20 USD has to be paid to the government. If a genetic resource for utilisation as defined in the Nagoya Protocol is being accessed, no fees have to be paid.	
Other permits prerequisite to obtain ABS permit	No		
IRCC (Internationally Recognised Certificate of Compliance)	No		

Criteria	Acquired information	Comments	Source
Have ABS permit(s) been issued in the country?	Yes	The information from the framework contract could be used to upload on the ABS-CH necessary for IRCC.	
ABS permit(s) issued by	No information		
Average timeline (from access demand to permit)	Timeline not defined	The average timeline is about two months (60 days), from the reception of the research proposal and the subscription of framework contract for access to GR, in the cases of scientific research purposes.	
MAT(s) signed	Yes	The Government and other supporting national institutions (universities and research centres), have established an agreement by clauses, according to the terms of the framework contract signed.	
MAT(s) to be signed with	Name of entity	Ministry of Environment At the moment, the Ministry of Environment is responsible for this process. Once the Scientific Research Platform is on function, the Secretariat of Higher Education, Science, Technology and Innovation (SENESCYT) will assume this competence.	
Standard MAT clauses	Yes	Clauses like: legal background, laws, justification, interpretation, definition terms and language, available documents, objectives and scientific team, duration, obligations and rights of the Parties, samples, responsibilities of damage, intellectual rights, restriction and confidentiality and other legal justifications	
PIC(s) granted	Yes	PIC is granted through a framework agreement of access to GR, taking into consideration the clauses correspondent to the MAT.	
PIC(s) to be granted by	Name (s) of entity	These 3 institutions are involved in this process: Ministry of Environment, Secretariat of Higher Education, Science, Technology and Innovation (SENESCYT) National Service of Intellectual Property (SENADI). Traditional knowledge Unit	

9.4 **Access Scenario Discussion**

Tab. 10: Access Scenario Discussion Ecuador

Case	**Parameter of the case**	
A cosmetic company from an EU member state informs the ABS authority of your country about its intention to start a cooperation with one of the indigenous peoples in your country. Your country is recognising the rights of granting PIC and negotiating MAT to indigenous peoples, if GR are accessed on their land, which are traditionally used by the indigenous peoples for cosmetic and medicinal use. The company will undertake R&D on the plants. Its policy is to keep any research results as confidential business information and not to apply for patents.	**user**	cosmetic company
	commercial or non-commercial intent	commercial
	is the user from a party	yes
	provider in country	farmers
	other actors involved	indigenous people
	IPLCs involved	yes
	aTK	yes
	location of access	land of indigenous people / in situ

The fictional case for Ecuador was not discussed due to time constraints and due to the fact that up to now, commercial access requests are not yet processed in Ecuador.

10 Access Procedures of France

Mr. Guillaume Faure, Deputy Head of Supervision of Impacts Office, Water and Biodiversity Directorate, Ministry for an Ecological and Solidary Transition

Fig. 16: Mr. Guillaume Faure

10.1 Country Presentation

Apart from France, more than 100 other countries have ratified the Nagoya Protocol. With its overseas territories rich in biodiversity (80 % of France's biodiversity is overseas), its chemical and cosmetic industry fond of new molecules and its very active public research, France is both a source country and a requesting country. Therefore, it was important for France to give a framework to the NP in its legislation.

Context

* 1992: Convention on biological diversity (CBD)

* 2006: pioneer ABS system in the National Park of Amazonia in french Guyana

* 2010: signing of the Nagoya Protocol (NP)

* 2011: France signed the NP

* 2014: - the NP entered into force

- Regulation (EU) 511/2014 of the European Parliament and of the Council

* 2016: loi n°2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages ("The restoration of biodiversity, nature and landscape law", August 8th, 2016) (https://www.legifrance.gouv.fr/eli/loi/2016/8/8/DEVL1400720L/jo#JORFSCTA00003301624). With this law, France ratified the NP (art. 46) and implementedABS on its territory (art. 37)

* 2017: - décret n°2017-848 du 9 mai 2017 relatif à l'accès aux ressources génétiques et

aux connaissances traditionnelles associées et au partage des avantages découlant de leur utilisation ("Decree n°2017-848 of May 9th 2017, regarding access to genetic resources and traditional knowledge and the sharing of benefits arising from their utilisation") (https://www.legifrance.gouv.fr/eli/decret/2017/5/9/DEVL1702693D/jo/texte). The decree precises the law, such as:

- finalization of the national procedures of declaration and authorization
- implementation of the european regulation
- Entering into force on July, 1st, 2017, of the national procedures all over the territory (overseas and mainland territory) established by the 2016 law.

-arrêté du 13 septembre 2017 fixant le contrat-type de partage des avantages découlant de l'utilisation de ressources génétiques prélevées sur le territoire national ("The September 13th, 2017 ministerial decision that set the standard contract regarding the use of natural resources on national territory and benefit sharing"): it sets a model contract;

-arrêté du 8 novembre 2017 relatif aux formulaires de déclaration et de demande d'accès aux ressources génétiques et aux connaissances traditionnelles associées (« The November 8th, 2017 ministerial decision on reporting and request forms regarding the access to genetic resources and traditional knowledge ») : it fixes the forms to be fullfilled by the applicants

* 2018 : arrêté du 20 mars 2018 relatif aux modalités d'instruction des demandes d'inscription des collections de ressources génétiques au registre européen des collections et aux modalités de contrôle des procédures de gestion y afférentes (« The March 20th, 2018 ministerial decision that sets the inquiry conditions regarding the registration requests of genetic resources collections into the european register as well as the control procedures at stake »)

Legal framework for ABS implementation

The 2016 law has defined a general scheme, 5 specific schemes and has established a list of exceptions that are outside the scope.

GR and TK excluded from access measures are:

"a) Human genetic resources

"b) GR collected outside the national territory and areas under French sovereignty or jurisdiction

c) GR covered by international instruments specializing in ABS that meet the objectives of the Convention on Biological Diversity, and which are not in violation thereof, such as the International Treaty on Plant genetic Resources for Food and Agricultre (ITPGRFA);

d) GR of species used as models in research and development

e) TK associated with GR that cannot be attributed to one or more traditional communities;

f) TK associated with GR whose properties are well known and have been used for a long time and repeatedly, outside of the traditional communities that share them;

"g) TK and techniques associated with the promotion methods defined under Article L. 640-2 of the French Rural and Maritime Fishing Code that are likely to benefit agricultural, forestry or food and seafood products;

The exchange and use for personal or non-commercial purposes of GR and associated TK within and between traditional communities and activities related to the protection of defence and national security interests are also outside the scope of the french ABS regulation.

A general scheme for GR and TK associated to GR removed from the french territory, used for research and development activities.

Specific schemes:

The 5 specific schemes are related to :

1) GR from domesticated or cultivated species as defined under 6) of Article L. 412-4;

2) GR of related wild plant species as defined under 7) of the same Article L. 412-4;

3) GR collected by genetic resource laboratories in the context of prevention, surveillance and fighting the health risks concerning animals, plants and food health safety within the meaning of 1) and 2) of Article L. 201-1 of the French Rural and Maritime Fishing Code;

The access to these 3 types of genetic resources ought to be regulated by the ministry for food and agriculture which finally decided, in 2018, not to regulate access to these genetic resources.

4) GR that are subject to forestry as governed by Article L. 153-1-2 of the French Forestry Code; a decree is being prepared by the ministry for food and agriculture;

5) GR collected by the laboratories to prevent and control the serious risks for human health as governed by Article L. 1413-8 of the French Public Health Code: the access will be regulated by the ministry of health, a text (decree) is still being prepared

Specific measures in french overseas territories:

French Polynesia (https://www.service-public.pf/diren/partager/code/) and New-Caledonia (North area (https://www.biodiversite.nc/attachment/229854/) and South area (https://www.provincesud.nc/sites/default/files/758331/Code%20de%20l%27environnement-version%20denv-2009-25%20APS%20M31.pdf)

French Guyana and Wallis-and-Futuna Islands have been designated by the 2017 decree as the two territories where traditional communities may own traditional knowledge ;

French overseas departments can be designated as competent authority for their territory, if they wish. None of them have made such a choice. As a result, the ministry for an ecological and solidary transition (MTES) is the competent national authority (CNA) for those territories.

Institutional framework for ABS implementation

Who grants PIC? Regarding genetic resources collected in the french territory, the State grants PIC; regarding access to traditional knowledge associated with genetic resources, a public entity representing the traditional community will negotiate with the user and then the State will grant PIC.

CNA :

- the Ministry for an ecological and solidary transition (Water and biodiversity department) is the CNA for the general ABS scheme; it is also the CNA that shall receive declarations of due diligence at the stage of final development of a product devel-

oped via the utilisation of genetic resources or traditional knowledge associated with such resources

- the Ministry for Research is the CNA that receives declarations of due diligence from all recipients of research funding involving the use of genetic resources and traditional knowledge associated with genetic resources

Focal point**:** the Ministry for an ecological and solidary transition (International and European affairs department)

Steps to access genetic resources / associated traditional knowledge

The general scheme for wild genetic resources distinguishes three procedures:

1. Access to genetic resources for research and development without any commercial purpose: a declarative procedure (see graphic):

the applicant must fulfill a form : «imprimé CERFA» n° 15786*01 (https://www.formulaires.modernisation.gouv.fr/gf/cerfa_15786.do), or online (– legal entities: https://www.demarches-simplifiees.fr/commencer/apa-declaration-pmorale; – individuals: https://www.demarches-simplifiees.fr/commencer/apa-declaration-pphysique)

preliminary and technical instruction by MTES (examination of the file completion, verification that the request falls within the scope)

decision within 2 months : either rejection (reasoned decision) or agreement through an ackowledgment of receipt sent to the applicant. This acknowledgment of receipt is then published («Bulletin officiel ») and sent to the ABS clearing house.

The applicant can access genetic resources once he has received this document.

The benefit sharing is, in that case, necessarily non-monetary: it can consist, for example, in taking actions of cooperation to research, teaching activities, by awareness-raising measures to staff or general public, etc.

2. Access for commercial purposes: an authorization procedure (See graphic, annex II):

the applicant must fulfill a form: «imprimé CERFA» n° 15785*01 (https://www.formulaires.modernisation.gouv.fr/gf/cerfa_15785.do), or online (legal entities: https://www.demarches-simplifiees.fr/commencer/apa-autorisation-pmorale; – individuals: https://www.demarches-simplifiees.fr/commencer/apa-autorisation-pphysique)

preliminary and technical instruction by MTES : examination of the file completion? in the scope?

the applicant and the MTES must negotiate an ABS agreement (4 months). In case of non agreement, the authorization is rejected;

in case of genetic resources collected in situ in a national park, the park board meeting must give a formal opinion within 2 months;

decision within 2 months after the agreement: authorization to access genetic resources. The authorization is then published (« Bulletin officiel ») and sent to the ABS clearing house.

The benefit sharing may be monetary or non monetary (negotiated in the agreement).

3. Utilisation of TK associated to genetic resources (no matter wether the research has a

commercial purpose or not): an authorization procedure:

the applicant must fulfill a form: « imprimé CERFA » n°15784*01 (https://www.formulaires.modernisation.gouv.fr/gf/cerfa_15784.do); preliminary and technical instruction by MTES: examination of the file completion? in the scope?

a public local entity (in French Guyana and Wallis-and Futuna-Islands) that is still to be designated, organizes a prior consultation with the traditional community (2 to 9 months). Following this, the applicant negotiates an agreement with the public local entity in order to define MAT

decision by MTES within 2 months after the agreement: authorization to access TK.

Collections:

In the case of collections of GR or TK associated with GR, established before the publication of the 2016 law, the procedures apply:

to any access that follows the publication of the 2016 law, to genetic resources for research and development without any commercial purpose (declaration);

to access genetic resources for commercial purposes (authorization), only in case of a new use (a new use is defined as any research and development activity with a direct commercial development objective and for which the activity area stands out from what which was previously covered by the same user with the same genetic resource or associated traditional knowledge. If there is no new use, then, there is no access procedure).

Implementation experience

Up to now, France has delivered 49 receipts to access genetic resources for research and development without any commercial purposes (56 more shall be delivered soon).

No authorization requests have been submitted until now (neither genetic resources nor traditional knowledge). So, no agreement has been negotiated at this point.

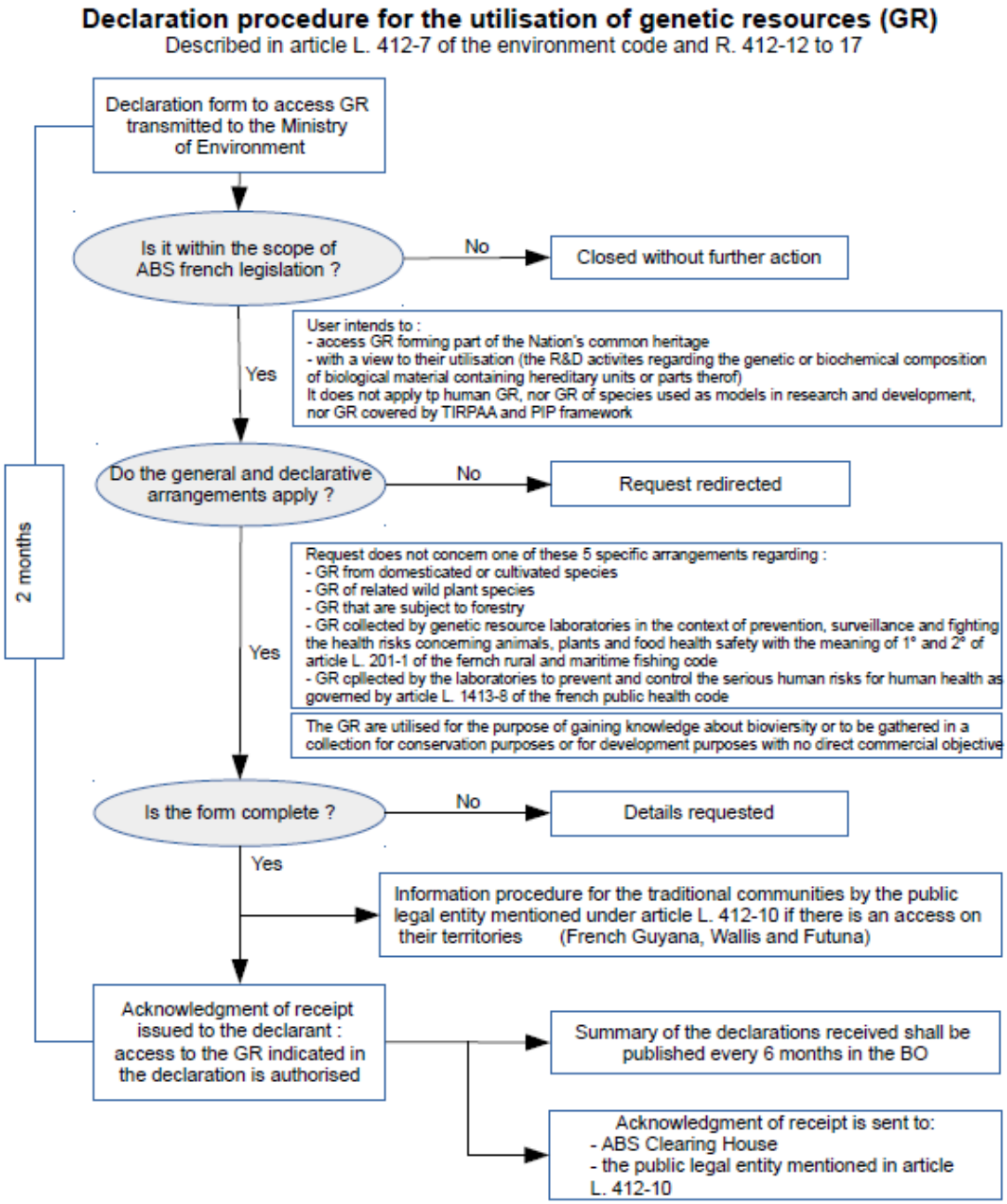


Fig. 17: Flow Chart France 1 (Declaration)

Authorization procedure for the utilisation of genetic resources (GR)

Described in articles L. 412-10 to 14 of the environment code and R. 412-18 to 27

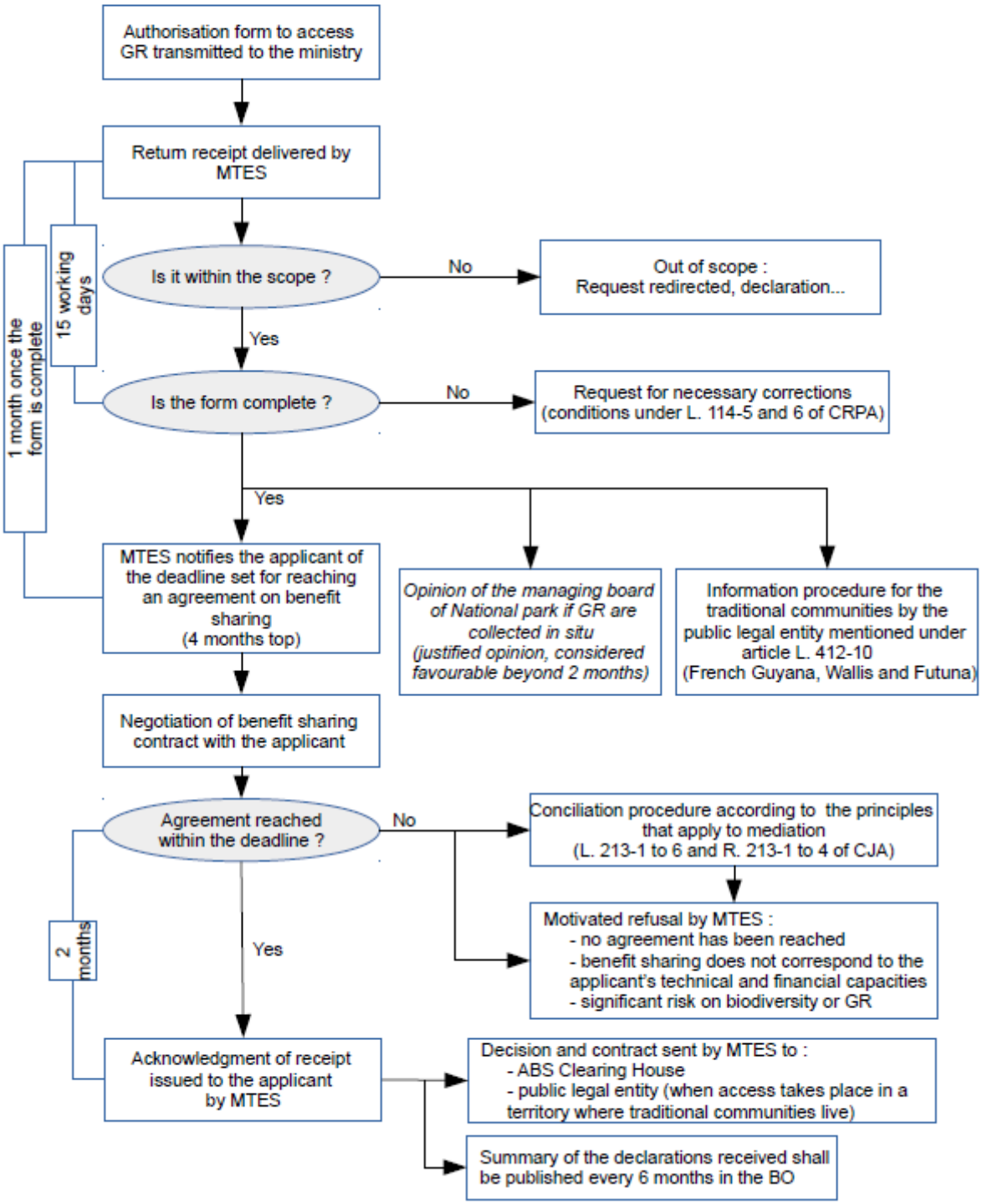


Fig. 18: Flow Chart France 2 (Authorization for GR)

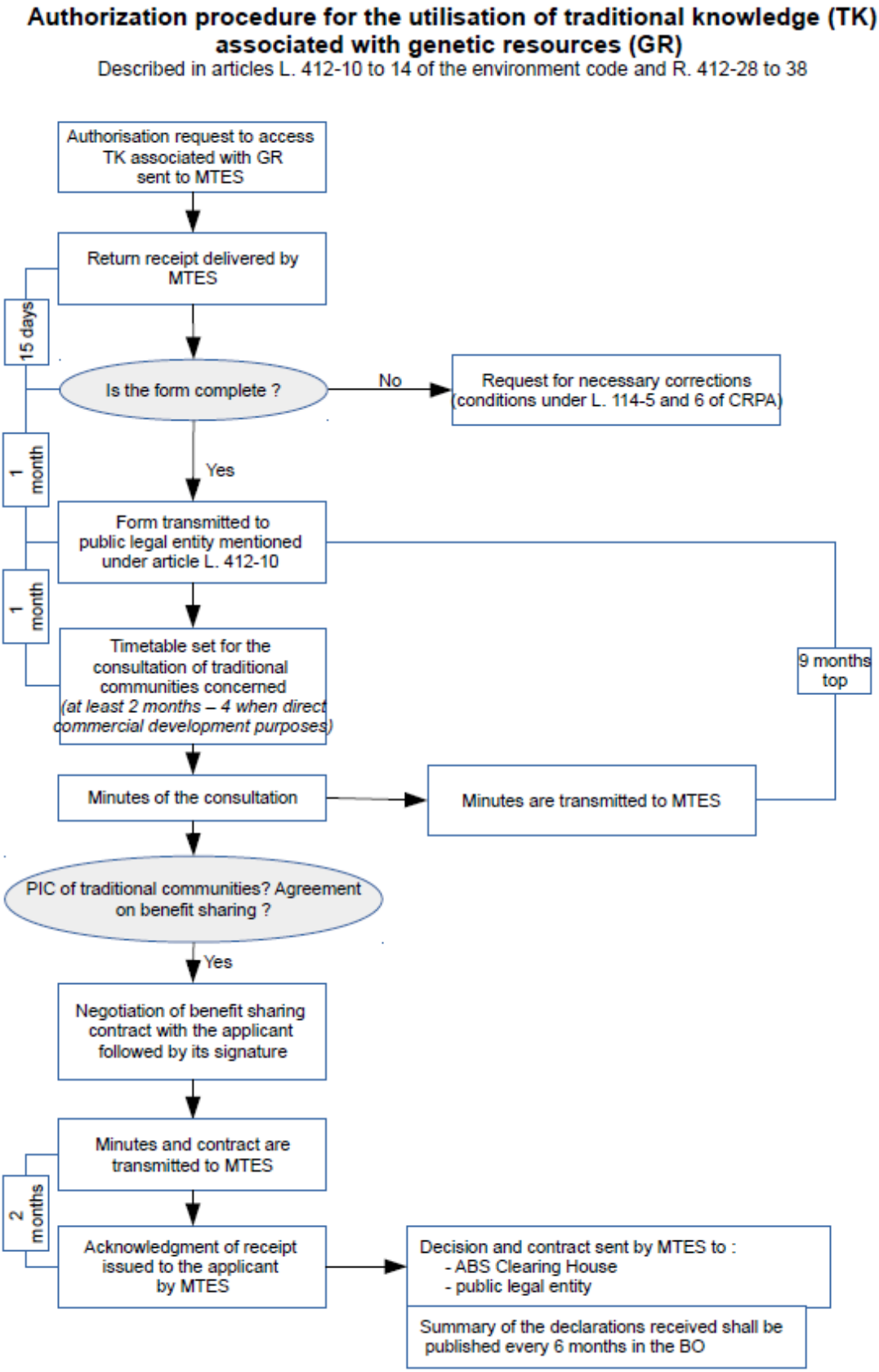


Fig. 19: Flow Chart France 3 (Authorization for aTK)

10.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- France has received 126 access enquiries for non-commercial purposes. So far there are no access requests for commercial purposes.
- In France, the geographical scope for ABS applies to mainland France and its overseas territories.
- France will create in Guyane a public entity which has the role of negotiating with traditional communities. ABS agreements are signed between the public entity and the applicant. Traditionalcommunities are not directly Parties to the agreement :the public entity will represent all communities of that territory. There will not be a leader of a specific community giving PIC.
- TK only applies to two territories in french overseas territories Guyane and Wallis- and Futuna. We assume that France has considered that in those two territories traditional communities were settled for ages in comparison to other territories such as La Réunion where local communities come from many different places.
- France has two CNAs regarding EU ABS Regulation :
- the Ministry of Environment (for the monitoring user compliance at the stage of final development of a product)
- the Ministry of Research (for the stage of research funding and for the implementation of the article 5 of the EU regulation about register of collections).
- Regarding national ABS measures, the user who wants to access a French genetic resource with a view of utilisation only has to establish contact with the CNA of the Ministry of Environment, which is the competent ministry to deliver the PIC and MAT.
- ABS is not triggered in France if the access and utilisation of a GR or a TK has occurred before the entry into force of the French legislation. In the case of collections formed before the publication of Act No. 2016-1087 of 8 August 2016, 2 different procedures apply :
    - to any access that follows the publication of the 2016 law, to genetic resources for research and development without any commercial purpose (declaration) ;
    - to access genetic resources for commercial purposes (authorization), only in case of a new use (a new use is defined as any research and development activity with a direct commercial development objective and for which the activity area stands out from what which was previously covered by the same user with the same genetic resource or associated traditional knowledge. If there is no new use, then, there is no access procedure).
- One needs to distinguish between the EU ABS regulation and French law. According to the EU regulation, the date of access is the trigger.

10.3 **Access Profile**

Tab. 11: Access Profile France

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	Yes		
Signatory	Yes	20/09/11	
NFP (National Focal Point)	Ms. Anca Leroy		
Contact NFP	anca.leroy@developpement-durable.gouv.fr +33 1 40 81 31 49		
CNA (Competent National Authority)	Access regulation: Ministry for an ecological and solidary transition / Directorat for water and biodiversity - Supervision of Impacts Office Mrs Hélène KERISIT, ABS policy officer (in charge of the ABS applications and the implementation of the french law on biodiversity) apa@developpement-durable.gouv.fr Phone: +33 1 40 81 92 34 Mr Guillaume POIRIER, deputy ABS policy officer apa@developpement-durable.gouv.fr Phone: +33 1 40 81 90 28 In New Caledonia : Haut Commissaire de la République en Nouvelle-Calédonie, 2, bis, Felix-Russeil BP36 98 835 Nouméa / BP M2 98 849 Nouméa. Due diligence obligations Stage of research fundings :Competent Authority regarding the due diligence declara-	https://esr-projets.adc.education.fr/apaeu/	

Criteria	Acquired information	Comments	Source
	tion (stage of research funding) and the registration of the collections at the EU level (EU ABS Regulation 511/2014): Ministry of Research / Ministère de l'Enseignement Supérieur, de la Recherche et de l'Innovation Contact person: Mrs. Florence HERVATIN, Ph.D, ABS Policy Officer florence.hervatin-queney@recherche.gouv.fr Phone: + 33 1 55 55 84 05 1 rue Descartes – 75 231 Paris Cedex 05 / FRANCE Stage of final development of products: Mrs Hélène KERISIT, ABS policy officer (in charge of the ABS applications and the implementation of the french law on biodiversity) apa@developpement-durable.gouv.fr Phone: +33 1 40 81 92 34 Mr Guillaume POIRIER, deputy ABS policy officer apa@developpement-durable.gouv.fr Phone: +33 1 40 81 90 28	https://webgate.ec.europa.eu/cas/login	
Contact CNA	ID as above		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	No	Process in the making	
ABS law	Yes	Loi n°2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages	
Specific access regulation	Yes	« The recapture of nature, landscape and biodiversity law » Loi n°2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages « Decree n°2017-848 of May 9th 2017, regarding the	

Criteria	Acquired information	Comments	Source
		access to GR and TK and benefit sharing as a result from their use" Décret n°2017-848 du 9 mai 2017 relatif à l'accès aux ressources génétiques et aux connaissances traditionnelles associées et au partage des avantages découlant de leur utilisation	
Specific access procedures (law or any defined process) for non-commercial use	Yes	Loi n°2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages Décret n°2017-848 du 9 mai 2017 relatif à l'accès aux ressources génétiques et aux connaissances traditionnelles associées et au partage des avantages découlant de leur utilisation	
English translation for users	No	English fill-in in the demand-forms will be accepted.	
Visualization of ABS procedure	Yes	3 different flow charts for declaration, authorisation of GR and authorisation of aTK	
Information on access procedure / regulations accessible through web-link	Yes	https://www.ecologique-solidaire.gouv.fr/acces-et-partage-des-avantages-decoulant-lutilisation-des-ressources-genetiques-et-des-connaissances	
Access demand form	Yes	**Declarations** https://www.formulaires.modernisation.gouv.fr/gf/cerfa_15786.do **Authorisations** - to access genetic resources: https://www.formulaires.modernisation.gouv.fr/gf/cerfa_15785.do - to access TK: https://www.formulaires.modernisation.gouv.fr/gf/cerfa_15784.do	
Specific access demand form for non-commercial purposes	Yes	**Déclarations** https://www.ecologique-solidaire.gouv.fr/acces-et-partage-des-avantages-decoulant-lutilisation-des-ressources-genetiques-et-des-connaissances	
Online application system	Yes	**Déclarations** - as a legal person: https://www.demarchessimplifiees.fr/commencer/apa declaration-pmorale - as a natural person: https://www.demarchessimplifiees.fr/commencer/apa declaration-pphysique	

Criteria	Acquired information	Comments	Source
		Autorisations as a legal person: https://www.demarchessimplifiees.fr/commencer/apaautorisation-pmorale - as a natural person: https://www.demarchessimplifiees.fr/commencer/apa autorisation-pphysique	
Compulsory documents for access demand application	No		
Submission of access application at	Ms. Hication at cess Mr Guillaume Poirier	apa@developpement-durable.gouv.fr	
Access fees	No		
Other permits prerequisite to obtain ABS permit	No		
IRCC (Internationally Recognised Certificate of Compliance)	Yes		
Have ABS permit(s) been issued in the country?	Yes	For non-commercial purpose	
ABS permit(s) issued by	CNA		
Average timeline (from access demand to permit)	Timeline not defined	2-4 months for declaration 5-9 months for authorisations	
MAT(s) signed	No		
MAT(s) to be signed with	Ministry for an ecological and solidary transition / representatives of the local		
Standard MAT clauses	Yes		
PIC(s) granted	Yes		
PIC(s) to be	Ministry for an ecologi-		

Criteria	Acquired information	Comments	Source
granted by	cal and solidary transition		

10.4 Access Scenario Discussion

Tab. 12: Access Scenario Discussion France

Case	Parameter of the case	
A university from Cameroon wants to undertake taxonomic research on indigenous plants. In addition to already collected samples in situ they intend – for comparative reasons – to access specimens and ethno-botanic literature from the herbarium of the Muséum National d'Histoire Naturelle of plants collected in Central and Western Africa.	**user**	university
	commercial or non-commercial intent	non-commercial
	is the user from a party	yes
	provider in country	MNHN
	other actors involved	none
	IPLCs involved	no
	aTK	no
	location of access	museum / ex situ

We consider that this access scenario is outside the scope of the French ABS legislation, because it is known that the plants' samples from the herbarium of Museum National d'Histoire Naturelle, based in France, have been collected in Africa, not in the French territory.

The article L.412-5 of French environmental code provides the list of activities that are outside the scope of the French ABS legislation: Legifrance

In particular, this list includes the access to genetic resources collected outside the national territory and areas under french sovereignty (II/b).

Access measures from the countries of central and western Africa should apply, if they exist: the user should verify the existing rules in those countries.

11 Access Procedures of Uganda

Mr. Akampurira Innocent Rolds, ABS Competent Authority, Uganda National Council for Science and Technology

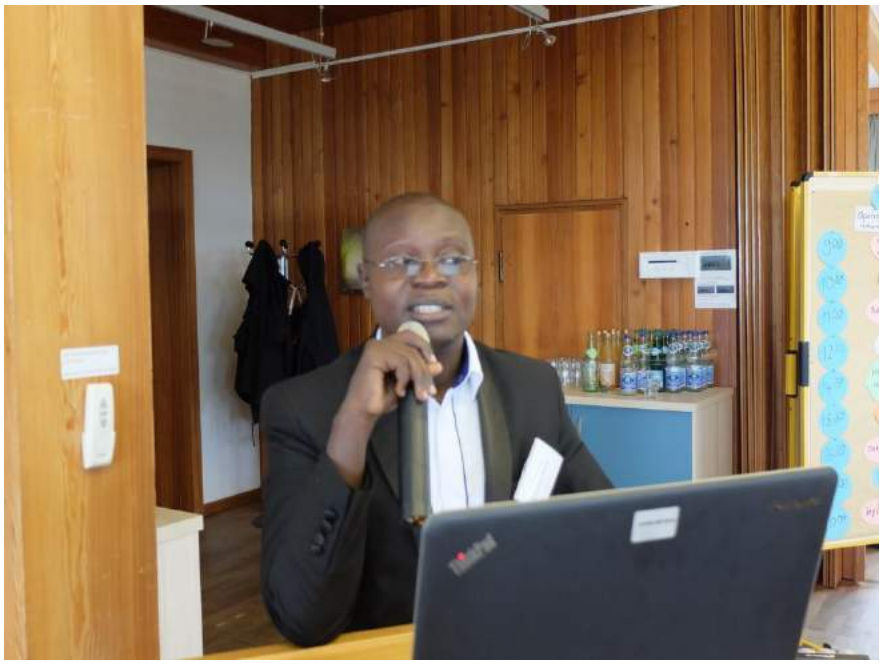


Fig. 20: Mr. Akampurira Innocent Rolds

11.1 Country Presentation

The following section was not available at editorial deadline.

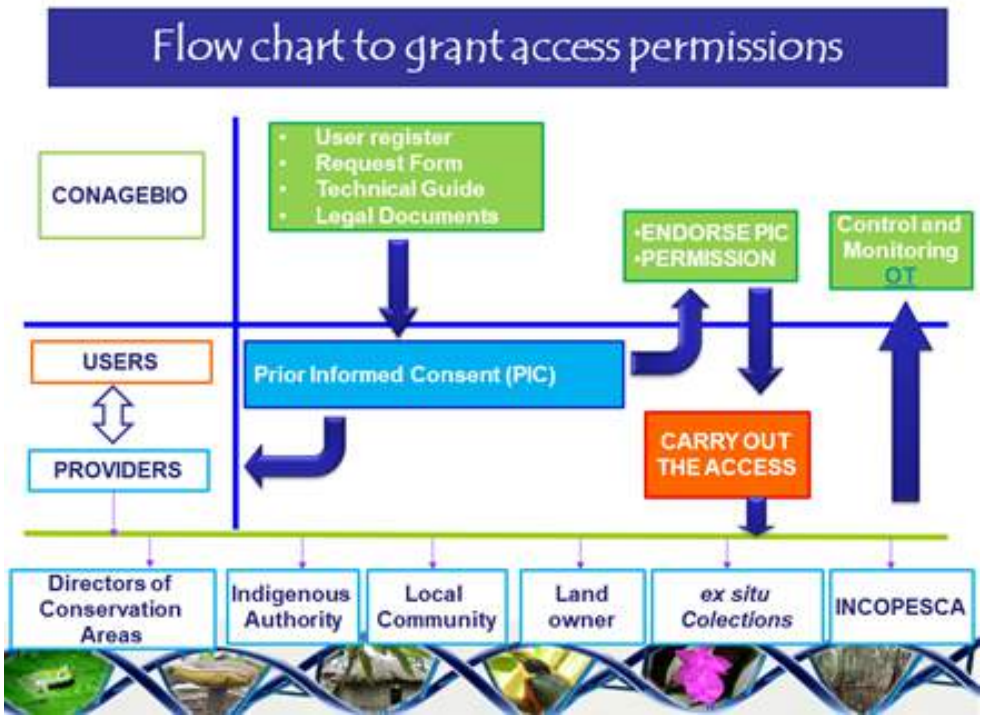


Fig. 21: Flow Chart Uganda

11.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- Environmental impact assessments need to be conducted when resources in Uganda are being accessed for commercial purposes. For example, in the case of Sandalwood not a large amount of harvesting is required, but the process of extracting oil also involves other resources (such as Eucalyptus) which affects other areas of the environment.
- In Uganda, the ABS law applies also to trade in commodities that are used for other purposes than consumption (i.e. not just for the purpose of R&D but in a broader sense). Most of the access requests in Uganda concern R&D.
- A research approval permit is needed from the CNA to conduct research in Uganda. A material transfer approval letter is also required for the transfer of material.
- Provider countries often list contact information or legislation on the ABS-CH. It would be very helpful if they also posted checklists, outlining clearly what is required for access in a given country as presented by Uganda. It would be useful if the SCBD could include a field “miscellaneous” in the country profiles of the ABS-CH to encourage countries to submit additional information on the national ABS procedures. Currently the SCBD is working on a new form for ABS procedures (basically key information that the user requires) which is expected to be available in November 2018. For the time being, additional documents (such as checklists) can be included in the field “ABS measures”.
- There is a need for capacity building on Intellectual Property Rights (IPR) issues of relevance to innovations and inventions resulting from GR and aTK.
- More awareness-raising on ABS obligations for checkpoints, lead agencies, IPLCs, local governments and civil society organisations is necessary.
- A research approval permit is needed from the CNA to conduct research in Uganda. A material transfer approval letter is also required for the transfer of material.
- There is a limited capacity in information sharing. Uganda has not yet established a national clearing house mechanism on ABS and to date there is no reliable national platform to support information sharing and public awareness on ABS issues.
- PIC is not required for research purposes but for all commercial purposes. PIC can be given by a variety of providers such as IPLC, private land owners, cultural communities, the government (in case access occurs in a National Park). The next step after the PIC is an accessory agreement.

11.3 **Access Profile**

Tab. 13 Access Profile Uganda

Criteria	**Acquired information**	**Comments**	**Source**
Party Nagoya Protocol	Yes	Uganda acceded to the Protocol on June 25th, 2014.	www.cbd.int
Signatory	No		
NFP (National Focal Point)	Mr. Francis Meri Sabino Ogwal	Natural Resources Manager (Biodiversity and Rangelands National Environment Management Authority	www.cbd.int
Contact NFP	sabinofrancis@gmail.com fogwal@nemaug.org +256 414 251 064, 5, 8 +256 77 2 517 045	Natural Resources Manager (Biodiversity and Rangelands) National Environment Management Authority	CBD website
CNA (Competent National Authority)	Uganda National Council for Science and Technology	Designated by the National Regulations on ABS No.30 of 2005	www.cbd.int
Contact CNA	info@uncst.go.ug +256 414 705 500/4; +256312 314 800	Executive Secretary	UNCST
CNA Deputy	Innocent Akampurira Ag. Deputy CNA	Senior Science Officer	
Contact CNA Deputy	Uganda National Council for Science and Technology Plot 6, Kimera Road, Ntinda P.O. Box 6884, Kampala Tel: +256414705500/44/0312314800; Fax:+256414234579 Mobile: +256782828271 Email: i.akampurira@uncst.go.ug; iakampurira@gmail.com		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	No	Not yet designated	

Criteria	Acquired information	Comments	Source
ABS law	No	Guidelines (since 2007) and regulations (since 2005) in place	www.cbd.int/abs/
Specific access regulation	Yes	Provided for in the National ABS regulations of 2005	www.cbd.int/abs/
Specific access procedures (law or any defined process) for non-commercial use	Yes	Provided for in the National ABS regulations of 2005	www.cbd.int/abs/
English translation for users	Yes	The National ABS regulations are in English	www.cbd.int/abs/
Visualization of ABS procedure	Yes		UNCST
Information on access procedure / regulations accessible through web-link	Yes	The National ABS regulations are in English	www.cbd.int/abs/
Access demand form	Yes	Form for Access Permit provided in the National ABS regulations	www.cbd.int/abs/
Specific access demand form for non-commercial purposes	Yes	Not provided in the ABS law but non-commercial use of GR (GR) by local communities provided for in the National ABS regulations. National Research Guidelines at UNCST	www.cbd.int/abs/
Online application system	No	Yet to be developed	
Compulsory documents for access demand application	Yes	The ABS law provides for PIC, Access Agreement, RC1, RS6 Forms, Proposal, Letter of Affiliation to a Local Organisation	
Submission of access application at	Name of institution	UNCST Functions of the institution and process described in the National ABS regulations	www.cbd.int/abs/
Access fees	Yes	PIC MAT (Case by case basis) Access Permit	

Criteria	Acquired information	Comments	Source
Other permits prerequisite to obtain ABS permit	Yes	MTA provided for in the National ABS regulations, EIA in specific cases	
IRCC (Internationally Recognised Certificate of Compliance)	No	Capacity building needed for CNA	UNCST
Have ABS permit(s) been issued in the country?	Yes	Access permit (Skybeam Africa used as pilot – accessing sandalwood)	
ABS permit(s) issued by	Name of institution	UNCST	
Average timeline (from access demand to permit)	Timeline defined	Within 60 days ABS guidelines	UNCST
MAT(s) signed	Yes	Moroto District Local Government	
MAT(s) to be signed with	Name of entity	Appropriate lead agency e.g.: International Livestock Institute, UWA, NFA, etc.	
Standard MAT clauses	Yes	The National ABS regulations outlines information that should be the MTA	
PIC(s) granted	Yes	Moroto District Local Government	
PIC(s) to be granted by	Name of entity	Appropriate lead agency Local Government Authorities and lead agencies	UNCST

11.4 **Access Scenario Discussion**

Tab. 14: Access Scenario Discussion Uganda

Case	**Parameter of the case**	
An EU based company for beauty products and fragrances intends to undertake R&D on essential oils from your country. They are especially interested in lemongrass and eucalyptus oil fractions for potential utilisation in fragrances and laundry detergent. The plants (leaves) are harvested by local farmers which sell the biological material to small cooperatives distilling the essential oils.	**user**	cosmetic company
	commercial or non-commercial intent	commercial
	is the user from a party	yes
	provider in country	local farmers
	other actors involved	cooperative
	IPLCs involved	yes
	aTK	no
	location of access	farmers land / in situ

The solution to the access scenario was not available at editorial deadline.

12 Access Procedures of the Dominican Republic

Ms. Luisa Arelis Castillo Bautista de Espinal, National Office of Industrial Property (ONAPI)

Ms. Lida Sibilio, Head of the Collection Division, Legal Direction of the Ministry of Environment and Natural Resources of the Dominican Republic

Fig. 22: Ms. Luisa Arelis Castillo Bautista de Espinal and Ms. Lida Sibilio

12.1 Country Presentation

Interesting remarks

Before 2018, the Dominican Republic did not have a specific regulatory framework regarding ABS. Since 2004 and as said, until 2018, we only had a Regulation for Investigation on Biodiversity that included a chapter for investigation on biodiversity with access to GR. That regulation is still in use, but only for applied investigations.

Before the ratification of the Nagoya Protocol we received financing from international environmental organisations for capacity building about ABS and the enhancement of institutional key actors in the country (ABS Capacity Development Initiative Caribbean -GIZ-).

The Ministry of Environment and Natural Resources on 2011 developed a National Strategy for Biodiversity Conservation and its Action Plan which will last until 2030, and also on 2015, the country started the “Program for Promoting the Economic Potential of Biodiversity in a Fair and Sustainable Way”, launched to implement the Nagoya Protocol in Central America and the Dominican Republic, funded by the German Cooperation (GIZ), within the framework of the Central American Environment Commission and Development (CCAD, by its initials in Spanish), a regional group that includes the Dominican Republic.

Legal framework

- CBD:

1. Signed on June 13th, 1992
2. Approval under Resolution N. 25-96 by our National Congress on October 2, 1996;
3. Ratification on November 26th, 1996
4. Entered into force on February 23rd, 1997

- The Nagoya Protocol

1. Signed on September 20th, 2011
2. Approval under Resolution N. 210-14 by our National Congress in June 26th, 2014.
3. Ratification on November 13th 2014
4. Entered into force on February 11th, 2015

- Dominican Constitution of June 13th, 2015:

Article 14 establishes that GR are part of the Nation´s Patrimony;

- Law 64-00 of August 18th 2000:

Article 16, numeral 44 defines GR as the group of genes that are present in wild populations, and or handled, that constitute the basis of biodiversity;

- Sectorial Law on Biodiversity N. 333-15, dated December 11th, 2015.

Article 1: Establishes as an objective of the law the regulation of the access to GR and the obligation to guarantee a fair and equitable ABS;

- Policy and Regulation on ABS of GR and TK,

approved by Ministry´s Resolution N. 0002-2018, dated January 15th, 2018.

CNA, Focal Point, PIC, MAT and Checkpoints:

- CNA/FP:

Ministry of Environment and Natural Resources. CNA for all the GR.

- PIC:

Ministry of Environment and Natural Resources;

If it is related to TK: Ministry + Local Community in question through a contract (MAT).

- MAT:

Granted with a contract to access GR, signed by the Minister and the User.

- Checkpoints:

1. Ministry of Environment and Natural Resources;
2. Ministry of Higher Education, Science and Technology

Other structures:

National Committee of Biodiversity (Decree N. 451-11 and N. 441-12)

The National Office for Industrial Property of the Dominican Republic

The National Office for Industrial Property of the Dominican Republic (ONAPI, by its initials in Spanish) in synergy with the Ministry of Environment and Natural Resources, and in order to meet the objectives and commitments assumed by the country, established in international agreements and in the national legal framework, and in order to preserve a sustainable use of biodiversity, on the patent requirements emphasizes the fact that if access to GR needs to be made, it must be done in the established legal form and that the benefits derived from it must be equally distributed.

Additionally, the patent application must contain information on the origin of the genetic material and / or aTK, the certificate of access to the genetic material, issued by the competent authority, whenever is required in the country of origin. The documents will be part of the background examination, where its relevance for the analysis of the application will be determined.

What is required in the Dominican Republic to access GR? Where to find it on the Regulation?

Articles 2.1 and 3.1 of our specific Regulation on ABS of GR from 2018 establish all the requirements. The procedure is the same for commercial and non-commercial use and the whole process takes up to 60 days.

Implementation experiences

So far, the Dominican Republic has 5 access to GR for investigation contracts; 4 with universities and 1 that includes benefit sharing with a pharmaceutical company (scorpion poison with therapeutic purpose).

Challenges

We all have different challenges when it comes to the implementation of Nagoya Protocol. The Dominican Republic needs more capacity building, especially when it comes to benefit sharing negotiations, elaboration of the ABS contracts, etc.

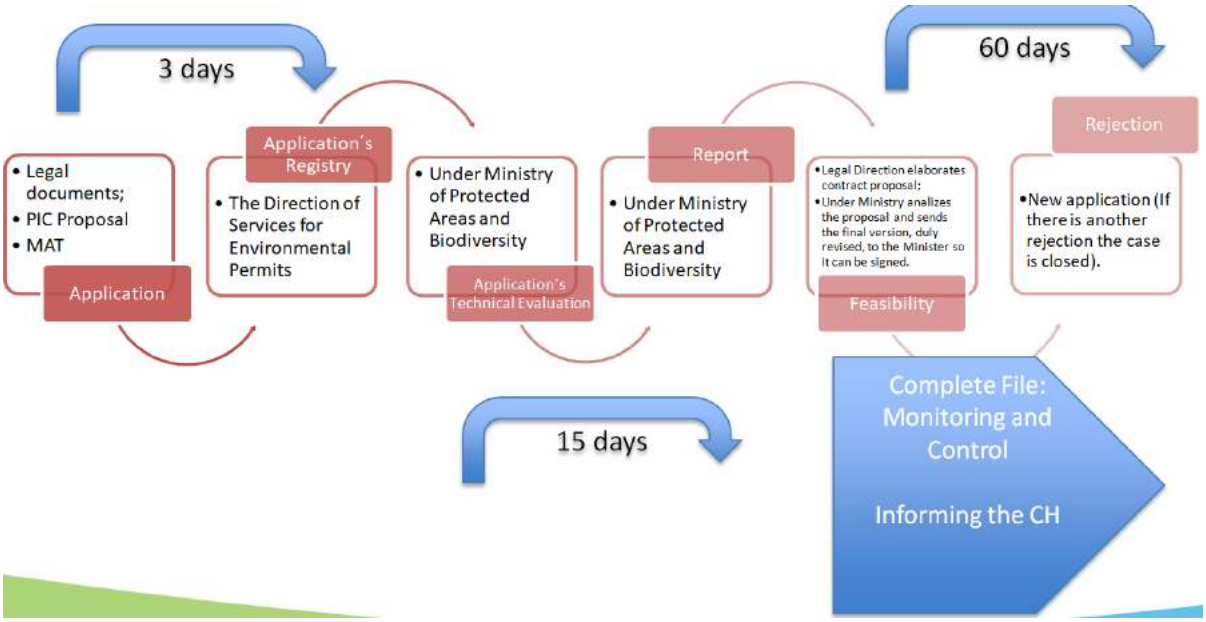


Fig. 23: Flow Chart Dominican Republic

12.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- In the Dominican Republic, a deposit (environmental bond) is required by the user who wishes to access GR / aTK for commercial purposes. The deposit amounts to 15.000 €. It does not seem to have a deterrent effect on users.
- The separation of benefit-sharing from the ABS application could be seen as an artificial separation because e.g. co-authorships are a form of non-monetary benefit-sharing. However, in the first contract (for research) there is a clause that in the eventual case the user finds something of commercial interest, he or she will need to return to the country and sign a second contract. The first contract can be concluded for up to three years. The second contract (for commercialization) can be an open-end contract.
- The checkpoints that are established in the Dominican Republic are not national access control measures checkpoints, but compliance checkpoints as foreseen under Article 17 of the Nagoya Protocol. So far, the Dominican Republic is one of the few countries apart from industrialized countries that has established such checkpoints.
- Like other countries, the Dominican Republic also encounters challenges in the implementation of the Nagoya Protocol. In particular, there is a need for more capacity-building on benefit-sharing modalities.
- In case an application is rejected for a second time, the case is closed.
- A specific case was presented: a user received an export permit for a specific GR for research purposes, including a clause for renegotiation in case of economic application. By chance the government learned years later that a commercial application had been developed without renegotiation. Since the user did not respond to requests for a renegotiation, the Ministry of Environment contacted the respective line Ministry responsible for issuing the phyto-sanitary certificate for the continued export. Based on an inter-ministerial agreement on all MEAs (Multilateral Environmental Agreements), the respective Ministry stopped issuing the phytosanitary certificate to the user and thus forced the user to renegotiate an ABS contract before allowing him to continue the exportation of the GR.

12.3 Access Profile

Tab. 15: Access Profile Dominican Republic

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	Yes	1. Approval under Resolution N. 210-14 of our National Congress in June 26th, 2014. 2. Ratification on November 13th, 2014 3. Entered into force on February 11th, 2015	
Signatory	Yes	1. Signed on September 20th, 2011	
NFP (National Focal Point)	Ms. Marina Hernandez	Ministry of Environment and Natural Resources	

Criteria	Acquired information	Comments	Source
Contact NFP	Marina.Hernandez@ambiente.gob.do recursos.geneticos@ambiente.gob.do marina_hernandez@hotmail.com +1 809 567 4300		
CNA (Competent National Authority)	Biodiversity Direction. Ministry of Environment and Natural Resources		
Contact CNA	marina.hernandez@ambiente.gob.do +1 809 567 4300		
CNA Deputy	No		
Contact CNA Deputy	Telephone Email	N/A	
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	Yes	Mercedes Peguero	
ABS law	No	Policy in Access to GR and Benefit Sharing (January, 2018)	http://ambiente.gob.do/wp-content/uploads/2018/04/REGLAMENTO-ACCESO-A-RECURSOS-GENETICOS-Publicacion.pdf

Criteria	Acquired information	Comments	Source
Specific access regulation	Yes	Regulation on Access to GR and Benefit Sharing (January, 2018)	http://ambiente.gob.do/publicaciones-oficiales/
Specific access procedures (law or any defined process) for non-commercial use	No	It is the same procedure for commercial and non-commercial use.	
English translation for users	No		
Visualization of ABS procedure	Yes		http://ambiente.gob.do/wp-content/uploads/2018/04/REGLAMENTO-ACCESO-A-RECURSOS-GENETICOS-Publicacion.pdf
Information on access procedure / regulations accessible through web-link	Yes		http://ambiente.gob.do/acceso-a-recursos-geneticos/
Access demand form	Yes		
Specific access demand form for non-commercial purposes	No		
Online application system	Yes		

Criteria	Acquired information	Comments	Source
Compulsory documents for access demand application	Yes		
Submission of access application at	Name of institution	Ministry of Environment and Natural Resources	
Access fees	No	There is an environmental bond for a value of one million Dominican pesos (US$20,833.00 / EU$15,625.00).	
Other permits prerequisite to obtain ABS permit	No		
IRCC (Internationally Recognised Certificate of Compliance)	Yes	One.	
Have ABS permit(s) been issued in the country?	Yes	One.	
ABS permit(s) issued by	Name of institution	Ministry of Environment and Natural Resources	
Average timeline (from access demand to permit)	Timeline defined	The whole process should take up to 60 days.	
MAT(s) signed	Yes		
MAT(s) to be signed with	Name of entity	Ministry of Environment and Natural Resources	
Standard MAT clauses	Yes		
PIC(s) granted	Yes		
PIC(s) to be granted by	Name of entity	Ministry of Environment and Natural Resources	

12.4 **Access Scenario Discussion**

Tab. 16: Access Scenario Discussion Dominican Republic

Case	**Parameter of the case**	
A researcher from a university in an EU member state informs the ABS authority of your country about his intentions to collect sponges from an unspoilt marine environment in a marine protected area. The researcher also informs you that he is CEO of a small start-up company attached to the university. Extracts of the sponges will be tested on cancer cells in the university lab. If successful, further tests on mice will be undertaken in his company.	**user**	researcher and CEO of start-up company attached to university
	commercial or non-commercial intent	commercial
	is the user from a party	yes
	provider in country	government
	other actors involved	none
	IPLCs involved	no
	aTK	no
	location of excess	marine protected area / in situ

Requirements for this type of researcher (academia and company owner) according to our Regulation on ABS/ the regulation on ABS in the Dominican Republic:

- Situation that can validly occur – Bioprospecting;
- The fact that it is an unspoiltmarine protected area does not affect the possibility for access. The only way in which that access would be more difficult is if the genetic resource is considered in danger or if the area of access is too fragile, and this is not the case;

So, the user needs to:

1. Complete the permission application form;
2. Complete the generals for the access contract, accompanied by his resume. Since he is the CEO of a company he must deposit the valid corporate documents, Commercial Registry, tax payment, etc., and attach a copy of his/her identity card or passport (EU member). Since the applicant is domiciled abroad, he should appoint a legal representative, resident in the country;
3. Indicate the title of the research project for access to GR and distribution equitable benefits and deliver a copy of the Research Project as approved by the institution sponsor.
4. Deliver an institutional letter or communication that endorses the technical execution of the investigation, if applicable, and the generals of the team of researchers of the project;
5. Indicate the name and complete identification of the national counterpart in the research activities.
6. Establish the objectives and purpose pursued by the project, and prepare description of the scope of the investigation;

7. Deliver a map of the location of the area and where the investigation will be conducted;
8. Indicate the approximate time that the whole process will last;
9. Identify the genetic material in which the user is interested and the approximate amount of material;
10. Establish the methods to be used for the collection of the material;

    In this case, transfer of material of the resource accessed to third parties is required, so it must be subject to the conditions and restrictions imposed by the Ministry in the contract.
11. Deliver the work schedule;
12. Submit an Affidavit signed by the applicant responsible for the investigation;
13. Deposit an environmental bond for a value of one million Dominican pesos (US$20,833.00 / EU$15,625.00);
14. Make a description of the use of GR or aTK that are intended to be used, if that is the case;
15. Submit the general information about the socioeconomic and environmental feasibility of the project;
16. Present a proposal for the distribution of monetary benefits and / or non-monetary benefits deriving from the use of the resource and / or TK associated, as the case may be.

- The user needs PIC
- A technical evaluation (required) / Consultation (if necessary) / conducted by the Under-Ministry of Protected Areas and Biodiversity
- Two (2) contracts; one to access the genetic resource and another one for benefit sharing (MAT)
- MAT granted by the Ministry only, since there is no Tk associated
- Needs Export Certificate: Customs
- ABS-CH: Internationally Recognised Certificate of Compliance (IRCC)
- Article 38 of our specific regulation on ABS establishes that those responsible for executing research for access to GR and distribution of benefits must respect the terms of international agreements related to conservation of the Biological Diversity and / or that are directed to the protection of the environment and the natural resources, such as: the CBD, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), among others; as well as any other agreements of which the Dominican Republic is a party.

13 Access Procedures of Bhutan

Mr. Chencho Dorji, Head of Bioprospecting and ABS Program / ABS National Focal Point, National Biodiversity Center, Ministry of Agriculture and Forests

Ms. Nima Om, Senior Legal Officer, Ministry of Agriculture and Forests

Fig. 24: Mr. Chencho Dorji and Ms. Nima Om

13.1 Country Presentation

Background

Bhutan is a small, landlocked country with an area of 38,394 sq.km situated on the southern slope of the Eastern Himalayas, bordering China to its North and India to its South, East and West. The country is almost entirely mountainous with altitudes ranging from 150 to 7500 metres above sea level within 220 kilometres between the southern and northern borders. Straddling the two major Indo-Malayan and Palearctic biogeographic realms, Bhutan is part of the Eastern Himalayan region which contains three global biodiversity hotspots and counted among the 234 globally outstanding eco-regions of the world according to a comprehensive analysis of global biodiversity by the World Wildlife Fund.

Currently, Bhutan has more than 70 percent of its land area under forest cover with over 50 percent of the total area secured as protected areas, biological corridors and conservation areas. Furthermore, Bhutan is committed to maintaining at least 60 percent of its total land under forest cover for perpetuity as enshrined in the Constitution. Bhutan has some of the most pristine and natural landscapes, characterized by a rich species diversity of about 5600 seed plant species, close to 200 species of mammals including 27 globally threatened species and approximately 700 bird species of which 18 are globally threatened. There are more than 300 species of medicinal and aromatic plants found in Bhutan.

Bhutan's current status of biodiversity conservation is a result of the far-sighted vision and leadership of our Kings and our rich tradition of living in harmony with nature throughout the centuries. Biodiversity conservation has always occupied a pivotal place in the country's development and this has been further strengthened through the formal adoption of the development philosophy of Gross National Happiness (GNH), which establishes environmental conservation as one of the four pillars of Gross National Happiness.

Bhutan became a party to the Convention on the Biological Diversity in 1995 after ratification by the 73rd session of the Parliament of Bhutan. Furthermore, Bhutan signed the Na-

goya Protocol in 2011 and became a party after ratification by the 9th session of the 1st Parliament of Bhutan in 2013 because of its strong commitment and efforts towards conservation of biodiversity which is guided by the development philosophy of Gross National Happiness. Some of the key objectives of the process were to secure value of Bhutan's biological resources and its associated TK and promote its conservation and sustainable use in order to promote peoples' participation and leadership in conservation of biodiversity.

Legal frameworks

Bhutan's commitment to environmental conservation has been translated into numerous Policies and Acts, and immortalized in the Constitution itself. However, following are few of the important policies/legislations governing ABS in Bhutan.

- The Biodiversity Act of Bhutan 2003 was enacted to regulate access to GR and aTK prior to the adoption of the Nagoya Protocol on Access to GR and the fair and equitable sharing of benefits arising from their utilisation. The revision of the Act has been completed and is submitted to the cabinet for endorsement for approval in the Parliament.
- The ABS Policy of Bhutan 2015 guides access to Bhutan's GR and aTK and the fair and equitable sharing of benefits arising from their research and commercial utilisation. It upholds the spiritual, cultural and traditional values of the Bhutanese people and it also promotes the ploughing back of benefits secured from access to Bhutan's biodiversity into conservation efforts. Until the Policy was adopted in 2017 as national policy it underwent ground testing for two years as an interim ABS policy.

Till date five executive orders in 2011, 2013, 2015, 2016 and 2017 were issued by the Ministry of Agriculture and Forests to implement ABS in the country while the interim ABS policy was being tested and the biodiversity Act was being revised.

Institutional arrangements

The following are the formally designated entities for the implementation of ABS in the country:

CNA: The Ministry of Agriculture and Forests, Royal Government of Bhutan is the CNA for discharging the functions conferred on it through the Secretary and is the final authority on access proposals.

NFP: The National Biodiversity Centre, Ministry of Agriculture and Forests is the NFP and the first contact point for access proposals. It receives, reviews and processes access proposals as well as makes information on ABS available for users and liaises with the CBD Secretariat in matters pertaining to Nagoya Protocol as required by the Article 13 of the Nagoya Protocol.

ABS-CH-Publishing Authority: The National Biodiversity Centre, Ministry of Agriculture and Forests is the designated ABS-CH-Publishing Authority for information related to ABS in Bhutan as required by the Article 14 of the Nagoya Protocol.

ABS Checkpoints: The Department of Intellectual Property, Bhutan Agriculture and Food Regulatory Authority and the National Biodiversity Centre are the designated checkpoints to monitor and support compliance of ABS requirements in line with the requirements of Article 17 of the Nagoya Protocol. The designated checkpoints will collect/receive information related to access and utilisation of GR and/or aTK ranging from PIC, source of the GR/aTK

to establishment of MAT and make such information available to the NFP, the CNA and to the ABS-CH, as appropriate.

While the state maintains sovereign rights and authority over the management of its GR and recognises the rights of holders of TK, the following are identified as the provider of GR and/or aTK within the ABS framework.

Department of Forests and Park Services: The Department of Forests and Park Services is the provider of genetic resource from government reserved forests and/or the protected area system.

Community Forest Management Group: A Community Forest Management Group is recognized as the provider when the genetic resource is accessed from a community forest.

NFP in consultation with the relevant community custodians or individuals: The NFP in consultation with the relevant community custodians or individuals is the provider for in-situ GR for food and agriculture and GR from private forestry.

NFP: The NFP is the provider when the GR are from ex-situ collections such as national gene banks, botanical gardens, national herbarium etc. In the event that a provider of GR and/or aTK is not identifiable, the NFP is deemed to be the provider.

Local community: A local community is the provider of TK held within a community unless an individual is recognised as the holder of the knowledge by that community. In cases where the TK associated with GR is held by more than one community, these communities are recognised as joint providers of TK. Where there is no identifiable provider, the NFP is deemed to be the provider.

Procedures for Access

Access to Bhutanese GR and/or aTK for research and commercial utilisation is divided into two phases: a scoping phase and an actualization phase with differing conditions for each phase.

Scoping phase: The scoping phase refers to the period before the actualization phase during which the user is granted access to GR and/or aTK for the initial exploratory phase of R&D with the aim of establishing market or research potential. The scoping phase is permitted through a Scoping Agreement executed between the NFP and the user once the access proposal is received and reviewed by the NFP and approved by the CNA.

Actualization phase: The actualization phase refers to the period when specific steps are undertaken to commercialize or engage in focused research on GR and/or aTK. It includes, but is not limited to applications for IPR, product development, and testing and marketing. It is governed by the ABS Agreement which is executed between the users and the providers of GR and/or aTK, under the guidance of the NFP.

Any user seeking access to the GR and/or aTK has to submit an access proposal to the NFP, who will review and assess the proposal for submission to the CNA for appropriate action. If the access proposal is rejected, the NFP will communicate the decision to the user. If the access proposal is approved, the NFP will facilitate access through execution of one of the following agreements:

1. Scoping Agreement
2. ABS Agreement
3. MTA
4. Standard MTA

The Scoping agreement, ABS agreement and MTA are model agreements that have been developed and used for implementing ABS in the country. Each agreement contains clauses which are termed 'model contractual clauses', which are the minimum requirements that should be included in these agreements to allow access and utilisation of GR and/ or associated TK.

1. Scoping Agreement: A Scoping Agreement is executed between the users of GR and aTK, and the NFP to permit the scoping phase, after the payment of a processing fee of Ngultrum 35,000.00 and a commitment fee of Ngultrum 350,000.00. A Scoping Agreement shall either be a standard contract or a negotiated contract or amongst others include the following model contractual clauses:

- Conditions for access and utilisation
- Specification and quantity of GR
- Information on collection sites of GR
- Confidentiality
- Change of intent
- Sharing of research information and results
- Transfer of research results or accessed GR to third parties
- Benefit sharing

2. ABS Agreement: An ABS Agreement is drawn between the provider and user of GR and/or aTK with the guidance of the NFP in the actualisation phase. A user may also directly enter into an ABS agreement without entering into a Scoping Agreement, where the NFP and the user considers it appropriate.

An ABS agreement is conditional to the payment of a processing fee of Ngultrum 35,000.00 if it follows a Scoping agreement. In cases where an ABS agreement is directly executed, then the commitment fee of Ngultrum 350,000.00 is also payable.

An ABS agreement shall amongst others include the following model contractual clauses:

- Conditions for access and utilisation
- Specification and quantity of GR
- Information on collection sites of GR
- Benefit sharing
- IPR
- Confidentiality
- Change of intent

- Sharing of product related information
- Transfer of research results or accessed GR to third parties
- Such other clauses as the CNA may consider

3. MTA: A MTA is a contract which is executed between the person seeking access to the material (applicant) and the recipient of the material with validation by the NFP. It is an expedited form of access when sought for non-commercial purposes such as academic research, exchange of samples between national and international institutions, sample testing for specific purposes if deemed appropriate by the NFP and approved by the CNA and such other cases as may be determined by the CNA.

The MTA contains the following model contractual clauses:

- Details of the applicant and recipient of GR
- Description of the GR
- Place of collection
- Destination of the material
- Terms of use of the GR
- IPR
- Change of intent
- Confidentiality
- Sharing of research information and results
- Transfer of research results or accessed GR to third parties
- Benefit sharing

4. Standard MTA: A Standard MTA (SMTA) is a standard contract developed by the secretariat of the International Treaty for Plant Genetic Resources for Food and Agriculture for use by parties wishing to provide and receive material under the multilateral system. It contains standard terms and conditions that ensures that the relevant provisions of the International Treaty are followed by individual providers and recipients of plant genetic material.

Exemptions under the ABS legislations in the country (Biodiversity Act of Bhutan 2003 and the ABS Policy of Bhutan 2015)

The Biodiversity Act of Bhutan 2003 and the ABS Policy of Bhutan 2015 covers the research and commercial utilisation of Bhutan's GR, their derivatives and/or aTK but does not apply to the access of human GR. Biological resources when traded, shared, exchanged and used as commodities are also exempted from the scope of ABS legislations. However, if these biological resources are later utilized as GR for research and/or commercial purposes, such utilisation is not exempted.

Further, the use, sharing and exchange of TK within and between local communities is exempted from the scope of ABS legislations unless such knowledge is utilized beyond its traditional context for commercial and/or research purposes.

Benefit-Sharing

Benefit-sharing refers to the sharing of benefits accrued from the access and utilisation of GR and/or aTK in a fair and equitable manner based on MAT, between the providers and users. The NFP is responsible for providing oversight during the negotiation process to ensure the fair and equitable sharing of benefits between the providers of such resources/aTK and the users. The benefits can be monetary or non-monetary in nature as listed below.

The monetary benefits consist of any or a combination of the following:

- Fees
- Up-front payments
- Milestone payments
- Payment of royalties
- License fees in case of commercialization
- Contribution to the Bhutan ABS Fund
- Research funding
- Joint ownership of relevant IPR
- Other monetary benefits

The non-monetary benefits consist of any or a combination of the following:

- Institutional capacity building
- Technology transfer and strengthening capacities for technology transfer
- Collaboration, cooperation and contribution in education and training
- Capacity building of local communities
- Other non-monetary benefits

Bhutan ABS Fund

The Bhutan ABS Fund was established in 2010 with approval from the Ministry of Finance to receive monetary benefits derived from the research and commercial utilisation of Bhutan's GR and/or aTK, in order to support the conservation and sustainable use of Bhutan's biodiversity and enhancement of rural livelihoods and offer a sustainable initiative to complement and offset the costs of conservation in the country. The first contribution to the Fund was made from the payment received from allowing access to GR, in this case, *Cymbidium erythraeum* to a user company in order to operationalize and understand the ABS regime. The primary objective behind the Fund is to ensure that access to GR and/or aTK results in the fair and equitable sharing of benefits arising from their utilisation, which in turn strengthens biodiversity conservation, promotes ownership and enhances community livelihoods.

The BABS fund is also an effective tool to garner support from local communities for the conservation and sustainable utilisation of biological resources and/or aTK, since communities can see tangible benefits of conservation, which further motivates them to participate in conservation efforts and also promote conservation stewardship. The Fund is used only for the conservation and sustainable use of Bhutan's biodiversity and/or aTK and enhancement of rural livelihoods.

Example of ABS agreements

There are four examples of ABS agreements implemented in the country till date as follows:

- Bipartite ABS agreement which is between the government and an international company or between the government and the local community.
- Tripartite ABS agreement which is between the government, a national private company and the local community; and between two government entities and the local community.

There is also ongoing scoping work between the government and an international company with the involvement of the local community which could result in a tripartite ABS agreement down the line and serve as another example of ABS agreement.

Example of a bipartite ABS agreement between the government and an international company:

An international company and NBC entered into a 'Memorandum of Agreement (MoA) on biodiscovery research and benefit sharing' allowing the company access to processed orchid flowers from a local community-based natural resources management group for the production of an anti-wrinkle cream. The monetary benefits received for the processed orchid flowers is channeled into the BABS fund while the royalty from the sale of products is deposited in the government treasury. The money in the BABS fund is used to support community-based conservation initiatives such as capacity building of local communities in orchid propagation and management.

Example of a bipartite ABS agreement between the government and the local community:

This is an ABS initiative implemented by NBC with the Dzedokha Phacheng Detshen, a local community holding TK related to a local ginger species, through the Nagoya Protocol Implementation Fund project funded by GEF-UNDP. In this ABS agreement, NBC is the user accessing the genetic resource and aTK from the provider, who is the Dzedokha Phacheng Detshen for developing wellness products. The local community and the NBC agree on the conditions of access and utilisation of the genetic resource and aTK through a series of negotiations, guided by the community protocol and the principles of ABS, as enshrined in the ABS policy of Bhutan 2015 and the Nagoya Protocol.

Some of the initial benefits ensuing from this ABS agreement to the local community are: capacity building of the local community in ABS as well as the cultivation and management of the ginger crop; and payment of premium prices for the harvested crop. It is foreseen that the community will reap additional benefits later when the product is commercialised. A portion of the benefit will also be channeled into the BABS fund as a symbolic contribution to the conservation of biodiversity as agreed in the ABS agreement.

Example of a tripartite ABS agreement between the government, a national private company and the local community:

This is also an initiative supported by the GEF-UNDP funded NPIF project wherein BioBhutan has access to the leaves of a Rhododendron sp. supplied through a local community group called Dzomdagam Ngomen Tshogpa facilitated by NBC for natural product development. The mutually agreed benefits received by the local community group through negotiations guided by their community protocol and overseen by the NBC are: payment of

premium prices by BioBhutan for the genetic resource; capacity building for sustainable harvesting; and sharing of a percentage of the annual gross profit from the sale of the products with the community. Additionally, a portion of the monetary benefit resulting from this ABS agreement will be received by the BABS fund as mutually agreed between the parties.

Example of a tripartite ABS agreement between two government entities and the local community:

This is also an initiative implemented with support from the GEF-UNDP funded NPIF project wherein NBC and Menjong Sorig Pharmaceuticals Corporation Ltd. (MSPCL) are partnering with two local community groups called Namther Throgmen Tshogpa and Tserim Yugel Sngomen Tshogpa. MSPCL has access to three different plant species for the production of natural products. MSPCL is granted access to the genetic resource based on MAT and conditions through negotiations with the local community groups with NBC maintaining oversight. The benefits received by the community groups in these ABS agreements are: payment of premium prices for the genetic resource accessed by MSPCL; capacity building for sustainable harvesting; and sharing of a percentage of the annual gross ex-factory sales of the products with the community groups.

Additionally, a portion of the monetary benefit resulting from the ABS agreements will be received by the BABS fund as mutually agreed between the parties.

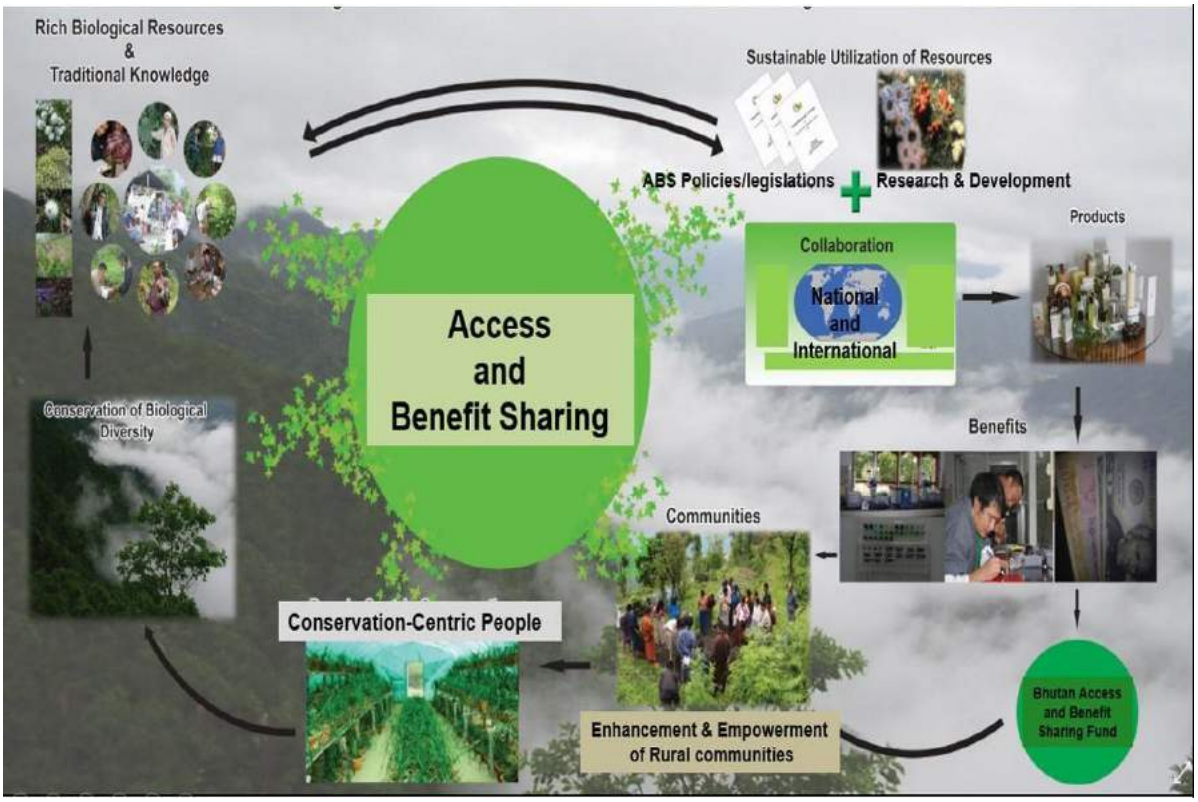


Fig. 25: Illustration of the Bhutan ABS model

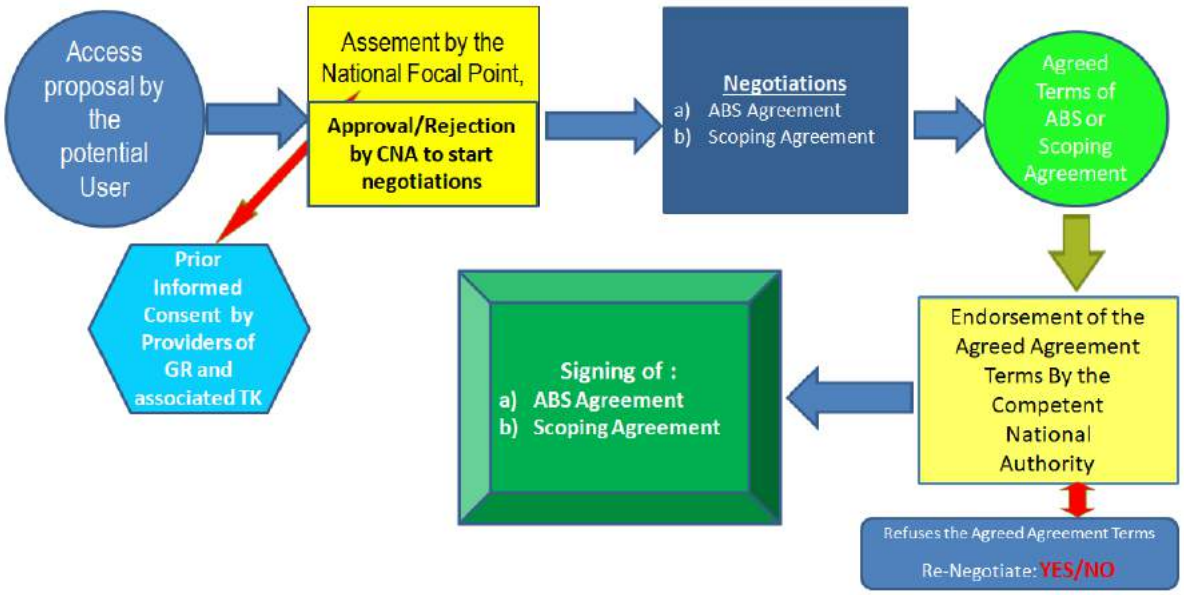


Fig. 26: Flow Chart Bhutan

13.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- A collaborating institution in Bhutan is required for foreigners in order to conduct research in Bhutan or on Buthanese GR.
- In Bhutan, the ABS NFP is responsible for signing an MTA (in comparison to more common understanding of MTA where it is mostly the collaborating partner that signs the MTA). The MTA is signed between the applicant, the recipient and the ABS NFP. The ABS NFP signs on behalf of the CNA. This process is done within ten days. This can now also be done electronically which is less time consuming than it used to be.
- In Bhutan, signing an MTA is a separate access procedure. MTA is an agreement between the Parties.
- Bhutan has established checkpoints according to Art. 17 of the Nagoya Protocol (the IP office) as well as a “national access control checkpoint”. The IP office checks whether the user has followed the ABS process or not (this applies to both foreign and national resources).
- The process of developing community protocols in Bhutan was challenging. In Bhutan, the community forest already had a law in place by that they were governed. This law however did not fulfill all needs because it does not address the issue of giving access, sharing benefits, etc. Therefore, Bhutan undertook ABS capacity-building activities with a view to helping communities. The approach was participatory. Efforts were put into discussing how the community in question will use and share the benefits they are receiving. This is clear when it comes to non-monetary benefits that are to be shared but it can be dangerous in the case of monetary benefits. The different needs and wants of the community in question first need to be determined.

- Integrating ABS in Bhutan has not been very challenging for Bhutan. The country has community forestry. Community management plans, procedures within the community forests and by-laws exist.
- Bhutan has received around 30 access requests for non-commercial purposes in 2017 (many for collaborative research, sample testing and taxonomic research). There is only a limited number of commercial access requests. Bhutan does not advertise to bring investors to the country. Currently there are 6 ongoing commercial agreements in place (3 are international, 3 developed through pilot projects and are thus of a national nature). Bhutan receives approximately 20 to 30 commercial enquiries a year. Bhutan is not advertising due to its limited capacity. There is limited staff (4 people work in the programme on ABS) and the country in the learning process on ABS.
- Bhutan raises a commitment fee of 5000 USD for the access of GR / aTK. There is an exemption possibility for researchers ("MTA access"). Changes will occur once the Bill is in Parliament. The processing fee for an access demand is 500 USD.
- Bhutan has a one stop shop approach. The ABS NFP oversees the whole process.

13.3 Access Profile

Tab. 17: Access Profile Bhutan

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	Yes	Bhutan ratified the Protocol on 30th Sep 2013.	ABS-CH
Signatory	Yes	Bhutan signed the Protocol on 20th Sep 2011.	ABS-CH
NFP (National Focal Point)	Mr. Chencho Dorji	Dr. Tashi Yangzome Dorji and Mr. Mani Prasad Nirola are the alternative NFPs.	ABS-CH
Contact NFP	dorjichencho@gmail.com yangzome2011@gmail.com manipra-sad52@gmail.com +975 17416770 +975 2 351417		ABS-CH
CNA (Competent National Authority)	Ministry of Agriculture and Forests	The functions conferred are discharged through the Hon'ble Secretary, Ministry of Agriculture and Forests	ABS-CH
Contact CNA	+975-2-322379 rinzindorji2@moaf.gov.bt		ABS-CH
CNA Deputy	No	So far, there is no fixed deputy CNA designated, however, when the Hon'ble Secretary is out of station, the designated offtg. Secretary would discharge his duties on the matter.	

Criteria	Acquired information	Comments	Source
Contact CNA Deputy	Telephone Email	N/A	
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	Yes	The National Biodiversity Centre is designated as the National Focal Agency for inventory and documentation of TK associated with biological resources. The elected local government acts as the competent authorities for local communities.	
ABS law	Yes	Yes, Bhutan has an ABS Law since 2003 known as The Biodiversity Act of Bhutan 2003. However, the Act is in the process of being revised with the Biodiversity Bill 2016 submitted for endorsement.	
Specific access regulation	Yes / No	Currently, the access regulation is in the draft form awaiting the endorsement of the Biodiversity Bill 2016.	
Specific access procedures (law or any defined process) for non-commercial use	Yes	Yes, there is a specific access process instituted in place for non-commercial use.	
English translation for users	Yes	Yes, there is ABS posters, MTA posters, ABS toolkit and documentaries developed for both users and providers.	
Visualization of ABS procedure	Yes	Yes, there is ABS posters, toolkit and documentary developed for both users and providers.	
Information on access procedure / regulations accessible through weblink	Yes	Yes, the information is available on http://www.nbc.gov.bt as well as www.moaf.gov.bt	
Access demand form	Yes	A form has been developed under the draft regulation but it is awaiting endorsement of the bill or the regulation.	
Specific access demand form for non-commercial purposes	Yes	A form has been developed under the draft regulation but will only be utilized after the endorsement of the bill or the regulation.	
Online application system	No	Currently, there is no online application system as such but the Centre does accept applications sent via email.	

Criteria	Acquired information	Comments	Source
Compulsory documents for access demand application	Yes	The form developed under the draft regulation does require certain compulsory documents.	
Submission of access application at	Name of institution	National Biodiversity Centre	
Access fees	Yes	A processing fee of Nu. 35,000/- (500 USD) and a commitment fee of Nu. 350,000/- (5000 USD) is charged.	
Other permits prerequisite to obtain ABS permit	Yes	Forest Permits	
IRCC (Internationally Recognized Certificate of Compliance)	No information	Bhutan has just designated checkpoints and is in the process of operationalizing the system to generate IRCC.	
Have ABS permit(s) been issued in the country?	Yes	Three pilot projects have been successfully implemented following the ABS regime.	
ABS permit(s) issued by	Name of institution	Ministry of Agriculture and Forests	
Average timeline (from access demand to permit)	Timeline defined	Average timeline for access demand to permit for a non-commercial purpose is set within a minimum of 10 working days but in most cases it's issued within few days. However, regarding access for commercial utilisation, the timeline is not defined as it dealt case by case but a response time since the receipt of the application is defined in the draft regulation. (30 days for review + 30 days for approval).	
MAT(s) signed	Yes		
MAT(s) to be signed with	Name (s) of entity	MAT is signed between the provider, the user and the NFP. However, when the provider is not identifiable, then the NFP signs the MAT with the User.	

Criteria	Acquired information	Comments	Source
Standard MAT clauses	Yes	Conditions for access and utilisation: • Specification and quantity of GR • Information on collection sites of GR • Confidentiality • Change of intent • Sharing of research information and results • Transfer of research results or accessed GR to third parties • Benefit sharing	
PIC(s) granted	Yes	PIC is understood as a process and not as a document.	
PIC(s) to be granted by	Name of entity	PIC is granted by the CNA.	

13.4 Access Scenario Discussion

Tab. 18: Access Scenario Discussion Bhutan

Case	Parameter of the case	
A researcher of a microbial collection in an EU member state informs the ABS authority of your country about his intentions to undertake a sampling excursion at various hot springs in your country. The springs are located in a protected area. Microbes will be analysed by biochemical and molecular methods in the EU member state for taxonomical purposes. The microbes will be stored in the collection and could be accessed by any user from any country.	**user**	researcher
	commercial or non-commercial intent	non-commercial
	is the user from a party	yes
	provider in country	government
	other actors involved	none
	IPLCs involved	no
	aTK	no
	location of access	Springs in a protected area / in situ

In Bhutan, any research needs to be conducted in collaboration with a national entity. Since the targeted microbe is from a protected area, once the application for access is submitted, the NFP will review the application and make an assessment if the collection is from a culturally importance place or a core protected area and if the user is reliable and if there is a commercial use foreseen etc. Once the assessment is complete, a recommendation will be submitted to the CNA for approval for non-commercial use. If approved, a MTA will be negotiated between the user and provider and endorsed by the NFP within 10 days. A sample transfer certificate would be issued as an export permit for the materials. Clear conditions of what you can do and what is not permissible would be mentioned in the MTA. If other users from any countries access the microbe and conduct R&D, then it would trigger ABS and fall within the ABS scope of Bhutan.

14 Access Procedures of Guatemala

Ms. Karen Jeanneth de la Cruz Orellana, Notary / Legal Adviser, Legal Affairs Unit, National Council of Protected Areas (CONAP)

Fig. 27: Ms. Karen Jeanneth de la Cruz Orellana

14.1 Country Presentation

Background

The State of Guatemala, through the Political Constitution of the Republic of Guatemala, issued by the National Constituent Assembly of 1985, in its Article 64, declared the conservation, protection and improvement of the nation's natural patrimony to be of national interest. The State will encourage the creation of national parks, reserves and natural refuges, which are inalienable. A law will guarantee their protection and that of the fauna and flora that exists in them.

In 1989, the Congress of the Republic of Guatemala issued the Law on Protected Areas, through which the Guatemalan Protected Areas System (SIGAP) was created, made up of all the protected areas and entities that administer it, in order to achieve the objectives in favor of the conservation, rehabilitation, improvement and protection of the country's natural resources and biological diversity. Apart from that, the National Council of Protected Areas (CONAP) was created to manage and coordinate the tasks of the SIGAP.

The SIGAP is made up of 338 protected areas nationwide, which is equivalent to 3,468,475.51 hectares, being 31.85% of the national territory. Biologically, it is a source of multiple goods and services (biodiversity, water, energy, food security, among others) that directly benefit the most important sectors of the national economy.

The objectives of the SIGAP are to avoid the loss of plant and animal species to maintain natural communities and the genetic flow. They are classified by categories, according to the Regulation of the Law of Protected Areas, contained in Government Agreement number 759-90, issued by the Presidency of the Republic of Guatemala (Category I: National Park

and Biological Reserve; Category II: Protected Biotope, Natural Monument, Cultural Monument, Historical Park; Category III: Multiple Use Area, Spring, Forest Reserve, Wildlife Refuge; Category IV: National Recreational Area, Regional Park, Scenic Routes and Routes; Category V: Private Nature Reserve; Type VI category: Biosphere Reserve).

In 1995, through Decree number 5-95 of the Congress of the Republic of Guatemala, it issued the ratification of the CBD and established the National Council of Protected Areas as a focal point, being responsible for topics related to biological diversity (Ecosystems, Species and Genes), as written in Article 15 of the CBD, the ratification of the Nagoya Protocol.

Guatemala is the center of origin and distribution of a great genetic diversity (genetic resources) of species typical of the existing ecosystems in the country. Many of these species were domesticated throughout the history of Mesoamerica and the cultures that developed there generated much knowledge about these species, which in the terminology of global management are identified as TK associated with GR. GR and aTK are in great interest to multiple users, whether for basic scientific research, bioprospecting or for the research for the development of products for commercial purposes, such as for the development of new varieties of cultivated plants, new breeds of domestic animals, pharmaceutical and cosmetic products, strains of microorganisms for the fermentation industry, among many other products.

Over time, there has been evidence of an appropriation or looting of GR and aTK throughout the world, becoming more evident in America with the conquest and colonization, which has served for the development of productive activities that have generated great profits at the expense of the use of GR and aTK generated by others, mainly IPLCs. An example is the production of cacao, where the most important production is found in the South Pacific and not in Mesoamerica, where it is domesticated and knowledge was generated for its cultivation.

GR have been essential for the development and evolution of the human species, and they play and will play an essential role for the current and future well-being of humanity, since these resources are the basis of many necessary inputs for our survival and well-being, as it is the food and the development of medicines. In such a way that the GR are legally patrimony of the states, declared by the Agreement on the Biological Diversity, and that to assure the exercise of that sovereignty over the GR precise activities are defined so that it derives in a fair and equitable distribution of the benefits of those who generated and possess knowledge about these species, and who, on the other hand, are responsible for the fact that this genetic diversity still persists in the territories that gave them origin.

The Nagoya Protocol, as a global instrument, defines some elements of the access management that are not defined in the articles dedicated to the process in the CBD. It was ratified by the State of Guatemala through Decree 6-2014 of the Congress of the Republic of Guatemala, published in the Official Gazette on March 3rd, 2014 and came into force in addition to the governmental agreement posting ratification saying that the CONAP should be the CNA for the purposes mentioned in the Protocol. The Nagoya Protocol is currently suspended by the Constitutional Court as of June 18th, 2016, due to a process of unconstitutionality of a General Law presented by several civil organizations and ancestral authorities that have been spoken out against the implementation of said protocol in Guatemala.

The suspension of the Nagoya Protocol is the result of the unconstitutionalities presented by ancestral authorities and the one designated by the political party called “Winaq, Amilcar

Pop" who argue that the Protocol leads to the privatization and commercialization of native seeds, as well as ancestral knowledge, based on which the procedure used for its approval within the Congress of the Republic was flawed.

The Ancestral Authorities of the Mayan peoples, the National Alliance for the Protection of Biodiversity (ANAPROB) and the National Network for the Defense of Food Sovereignty of Guatemala (REDSAG) demand the total suspension of the Nagoya Protocol, as well as respect for indigenous forms of organization who filed another unconstitutionality action, justified in their concern that this could lead to the introduction of transgenic seeds, in addition that for its ratification there was no consultation with indigenous peoples.

The CONAP has respected the suspension of the Nagoya Protocol until the final resolution of the Constitutional Court to establish the mechanism of socialization to the ancestral communities of Mayan peoples and other communities that are in the national territory, in order to elaborate if the case is the new proposal of initiative of Law so that the same one is presented before the Congress of the Republic.

Currently, the specific procedures for access to GR and aTK are not fully established and can not be used due to the suspension. However, other procedures are already established for Research Licenses, Collecting Licenses, Transport Licenses and Export Licenses related to any research activity associated with the biological diversity of Guatemala which includes access and use of GR. The use of these licenses is based on legislative and administrative regulations in force for Guatemala, such as:

- Law on Protected Areas and its Reforms (Decree number 4-89 of the Congress of the Republic of Guatemala);
- Regulation of the Law of Protected Areas (Government Agreement number 759-90, issued by the Presidency of the Republic of Guatemala);
- Norms for the approval of researches and researchers (Resolution number 027/2001, dated April 26, 2001, issued by the Executive Secretary of the National Council of Protected Areas), among the most relevant.

Even if the mechanisms for obtaining PIC are being prepared, obtaining the Research Licenses and Collecting Licenses must be processed by the CONAP before carrying out the research and collection activities, so that the obtaining of these licenses are considered as the PIC for access to GR.

The CNA may require additional information from the applicant of the Research Licenses and Collective Licenses, regarding the potential use that will be accompanied by the results and collections obtained during the research activity. In the same way, it may require the applicant to reveal the research activities to the IPLCs in the area where the investigation is intended, in order that the applicant of the licenses presents evidence on knowledge and consent by the IPLCs to the CNA, so that the research activities are developed in the territories with their presence. The CNA, together with the applicant, can then define how the socialization process, during which the CNA will provide permanent accompaniment, will be carried out.

After the Research and Collection Licenses are issued, the applicant may request the CNA to issue the Licenses of Transportation and Exportation of the biological material collected, which must be according to the content of the project that has been approved by the issuance of the Research License and Collection License.

Application for a License to Conduct Research

1. The application form is sent to the user.
2. The CNA receives the completed application form and a proof of payment: Q.800.00 (81,97 €) in the case of foreigners or Q.400.00 (40,98€) for non-academic nationals; researchers from national academics are exempt. Users should not send back forms that do not complete the following documentation:
    - Preliminary research
    - CV of the principal investigator
    - Letter of endorsement from a Guatemalan university or another institution of recognized prestige in the field of national environment which is accepted by the CONAP. The endorsement must be signed by a head of department in which he needs to indicate that he knows about the work, that he agrees with it and that he acts as a responsible or as a counterpart of the project. For this purpose, the head of department must receive advice from an expert according to the subject. It should be noted where the collected sample should be used afterwards.
    - Authorization letter or permission from the administrator when the investigation is carried out in protected area.
    - Identity card (passport for foreigners) of the principal investigator and their companions.
    - The researcher must commit to deliver copies of final reports to the CONAP.
3. The Director of the Wildlife Department of the Central of the respective section (Flora, Fauna or Hydrobiological) of the CONAP returns the application form after evaluating the draft and dictate.
4. The Director of the Legal Department issues the corresponding opinion and resolution and this is then transferred to the Executive Secretary for approval and signature of the resolution.
5. The Executive Secretariat transfers the file back for the registration of the researcher to the Legal Department.
6. The Legal Department transfers the file back and proceeds to issue the Research and / or Collection License.
7. The Director of the Wildlife Department transfers the research license to notify the user and delivers the corresponding Licenses.

Application for the Wildlife Collection or Use License

1. The application form is sent to the user.
2. The CNA receives the completed application form and a proof of payment: Q25.00 (2,56 €) + the rate for the use of the requested species, when appropriate. Users should not send back forms that do not complete the following documentation:
    - In the case of commercial or reproductive exploitation, the plan of management of the species has to be developed by a professional technician regent and duly registered. Apart from that, an environmental impact study has to

be developed (Article 48, Law on Protected Areas). The CONAP Breeder Farms should as well review the regulations for indications of how to develop the management plan and the conditions for obtaining the breeding stock (if the collection will be done in the wild, it will be necessary to carry out population censuses of the selected species before).

- In the case of scientific collection, the user oftenly has to submit the record of the investigation. The user must also indicate to which collection he will deliver reference specimens of each species.

3. The file is transferred to the Director of the Wildlife Department of CONAP who transfers it to the respective Section (Flora, Fauna or Hydrobiological) to issue a corresponding opinion.
4. If the technical opinion is appropriate, the Director of the Wildlife Department issues the Collection License and transfers the file. If the technical opinion is not appropriate, the Director of the Department of Wildlife transfers the file to notify the user.
5. The Collection License is then sent to the user and the user returns the file to the Wildlife Department.
6. The Director of the Wildlife Department orders a visit to the field to evaluate compliance with the management plan. No new licenses should be extended if there was a breach of the management plan in previous licenses.

14.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- The NP is currently suspended in Guatemala. Therefore, there is currently no possibility to attend any incoming access requests. CONAP can still grant access on the basis of pre-Nagoya legislation from 1989. There are 18 ongoing cases.
- So far, Guatemala has only made experience with non-commercial access requests.
- The endorsement of a national research institute or similar is needed for any access request.
- Altogether, 4 different permits (for research, collection, transport and export) are currently needed for access to GR.
- Currently there is no mechanism for sharing benefits with local communities. Guatemala conducts many ABS awareness-raising activities for IPLCs with a view to informing them about potential benefit-sharing modalities.

14.3 **Access Profile**

Tab. 19: Access Profile Guatemala

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	Yes		https://absch.cbd.int/countries/GT
Signatory	Yes	Suspended since June, 2016	https://absch.cbd.int/countries/GT
NFP (National Focal Point)	Mr. José Luis Echeverría Tello		https://absch.cbd.int/countries/GT
Contact NFP	echeverriatellolo@gmail.com otecbio@conap.gob.gt +502 1547		https://absch.cbd.int/countries/GT
CNA (Competent National Authority)	National Council Protected Areas -CONAP-		https://absch.cbd.int/countries/GT
Contact CNA	+502 24226700 +502 24226700 otecbio@conap.gob.gt mailto:megadiversidad@gmail.com		https://absch.cbd.int/countries/GT
CNA Deputy	Yes	Ing. Elder Manrique Figueroa Rodríguez, the legal representative of the National Council of Protected Areas	
Contact CNA Deputy	+502 24226700 +502 24226700 otecbio@conap.gob.gt megadiversidad@gmail.com		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	No		
ABS law	No		

Criteria	Acquired information	Comments	Source
Specific access regulation	Yes	At the moment, the access regulation is based on the conventional system (law from 1989) because the NP is currently suspended. Nevertheless, Guatemala is working on drafts for an ABS policy and the respective legislation.	RESOLUCION No.ALC 027/2001
Specific access procedures (law or any defined process) for non-commercial use	Yes		RESOLUCION No. ALC 027/2001
English translation for users available	No		
Visualization of ABS procedure	Yes		RESOLUCION No. ALC 027/2001
Information on access procedure / regulations accessible through web-link	Yes		RESOLUCION No. ALC 027/2001
Access request form	Yes		RESOLUCION No. ALC 027/2001
Specific access demand form for non-commercial purposes	Yes		RESOLUCION No. ALC 027/2001
Online application system	No		
Compulsory documents for access demand application	Yes	Documents (application form for research related collection of GR with respect to flora and wildlife) can be found under the provided link:	RESOLUCION No. ALC 027/2001
Submission of access application at	Name of institution	The National Council of Protected Areas	RESOLUCION No. ALC 027/2001

Criteria	Acquired information	Comments	Source
Access fees	Yes		RESOLU-CION No. ALC 027/2001
Other permits prerequisite to obtain ABS permit	No	Export permit Collection permit Transport guide (According to the GR in question, some or all of these additional permits need to be obtained. They can be obtained during or after the ABS permit process).	http://www.chmguatema-la.gob.gt/images/Exportaci%C3%B3n_Importaci%C3%B3n.pdf http://www.chmguatema-la.gob.gt/images/Licencia_de_Colecta.pdf http://www.chmguatema-la.gob.gt/images/Gu%C3%ADa_de_Transporte.pdf
IRCC (Inter-nationally Recognised Certificate of Compliance)	Yes		https://absch.cbd.int/countries/GT
Have ABS permit(s) been issued in the coun-try?	Yes		https://absch.cbd.int/countries/GT
ABS per-mit(s) issued by	Name of institution	National Council of Protected Areas (Legal represent)	
Average timeline (from access de-mand to permit)	Timeline defined	It depends on the purpose of the research (3 months to 1 year)	
MAT(s) signed	Yes		https://absch.cbd.int/countries/GT

Criteria	Acquired information	Comments	Source
MAT(s) to be signed with	Name of entity	National Council of Protected Areas	https://absch.cbd.int/countries/GT
Standard MAT clauses	No		
PIC(s) granted	Yes		
PIC(s) to be granted by	Name of entity	National Council of Protected Areas	https://absch.cbd.int/countries/GT

14.4 Access Scenario Discussion

Tab. 20: Access Scenario Discussion Guatemala

Case	Parameter of the case	
A researcher from a university in an EU member state informs the ABS authority of your country about his intentions to start a 10-year sampling project in the national waters of your country. The research project is on detecting climate change effects on plankton populations. Every year, plankton will be sampled and population DNA profiles be created in the laboratory of the vessel. The results will be published in international journals; the DNA sequences will be stored in a public data bank.	**user**	researcher
	commercial or non-commercial intent	non-commercial
	is the user from a party	yes
	provider in country	government
	other actors involved	none
	IPLCs involved	no
	aTK	no
	location of access	national waters / in situ

The researcher (user of GR) must present his request to the CONAP complying with the requirements. If the user is an international user, he must present the endorsement from a national university.

After presenting the file, the CONAP must determine if the investigation is carried out in a territory defined as national (only in national territory the investigation can be done with the endorsement of the CONAP), if aTK is included (in the present scenario probably not, but this must be deepened), if the research has economic interests and see if the collection methodology puts the plankton at risk (the previous technical answer would probably be “No” since the plankton is not at risk of extinction and exists in huge quantities). All these conditions must be determined based on the research protocol that is presented though.

When all of these things are cleared up, the CONAP issues Research and Collection licenses, with which the user can later process Transportation and Export licenses.

If the investigation merits an administrative contract between the user and the CONAP, in relation to the use of the data (Guatemala still does not have specific regulations for GR, only internal), an administrative contract would have to be signed, in which the government

could indicate restrictions regarding species of economic and biological interest (e.g. the government does not want the information obtained from the plankton study to be published in information banks of public genetic sequences). This contract would be equivalent to the MAT, so that the government lets the user do his research, but before sharing the information in a "public data bank", the government will tell the user on which species he is allowed to publish the information and on which he is not, for example. The government, so to speak, is putting the user under conditions to develop the activity, because states have sovereign rights to their resources, which is what the CBD promotes, among others.

The procedure would be as following:

1. The application form is sent to the user.
2. The CNA receives the completed application form and a proof of payment (Q.800.00 (81,97 €) in the case of foreigners or Q.400.00 (40,98 €) for non-academic nationals; researchers from national academics are exempt). Users should not send back forms that do not complete the following documentation:
    - Preliminary research
    - CV of the principal investigator
    - Letter of endorsement from a Guatemalan university or another institution of recognized prestige in the field of national environment which is accepted by the CONAP. The endorsement must be signed by a head of department in which he needs to indicate that he knows about the work, that he agrees with it and that he acts as a responsible or as a counterpart of the project. For this purpose, the head of department must receive advice from an expert according to the subject. It should be noted where the collected sample should be used afterwards.
    - Authorization letter or permission from the administrator when the investigation is carried out in protected area.
    - Identity card (passport for foreigners) of the principal investigator and their companions.
    - The researcher must commit to deliver copies of final reports to the CONAP.
3. The Director of the Wildlife Department of the Central of the respective section (Flora, Fauna or Hydrobiological) of the CONAP returns the application form after evaluating the draft and dictate.
4. The Director of the Legal Department issues the corresponding opinion and resolution and this is then transferred to the Executive Secretary for approval and signature of the resolution.
5. The Executive Secretariat transfers the file back for the registration of the researcher to the Legal Department.
6. The Legal Department transfers the file back and proceeds to issue the Research and / or Collection License.
7. The Director of the Wildlife Department transfers the research license to notify the user and delivers the corresponding Licenses.

15 Access Procedures of Benin

Mr. Melkior Kouchade, ABS National Focal Point, Ministry of the Environment and Sustainable Development

Mr. Mensah Bienvenu Célestin Bossou, Executive Director, NGO CeSaReN

Fig. 28: Melkior Kouchade and Mr. Mensah Bienvenu Célestin Bossou

15.1 Country Presentation

Setting the context

Benin has ratified the Nagoya Protocol and put in place a number of tools to frame its implementation in administrative, legislative and political terms. This was preceded by an identification of the key players to be involved, as well as a long campaign to raise awareness, information and analysis of the Nagoya Protocol's outlines and its significance for the country. But also, by an analysis of the current political, legislative and administrative framework in Benin with the aim of guiding strategic choices for the implementation of the Nagoya Protocol in Benin.

Benin has set up an inter-ministerial committee to coordinate all the thinking leading to the validation of an ABS national strategy. This interdepartmental committee will evolve into an interinstitutional committee and serve more in terms of better political involvement and administrative coordination. In fact, Benin defined the management bodies of the Protocol by providing for a committee.

The degree of complexity of the ABS process calls for compromise and strategic choices that are realistic and achievable in the operational. A number of options relating to (a) the recovery and/or protection system, (b) the role of the State in the negotiation of contracts and (c) the protection of traditional knowledge, were first to be lifted. The ABS national Strategy has mandated the establishment of a specific ABS law that governs the exploitation of all genetic resources including plant genetic resources for Food and Agriculture (PGRFA) as well as the associated traditional knowledge (aTK). Since the introduction of such a law could be too long, the need to develop a regulatory framework and transitional administrative measures to ensure legal certainty and transparency in ABS appeared essential.

To this end, Benin has developed and has adopted in the Council of Ministers guidelines to frame access to genetic resources and associated traditional knowledge. These guidelines

are likely to be reviewed or revised as experience in access and benefit-sharing is acquired and where necessary and do not impede taxonomic research as defined in the Global Taxonomy Initiative.

The ministry in charge of the environment is the national correspondent for ABS. For the implementation of the Directives, the ABS Focal Point operates as a competent national authority. To this end, it shall establish a focal point, including, in particular, the focal point for ITPGRFA, the national authority responsible for ITPGRFA, and, depending on the nature of the requests, representatives of the structures responsible for the management of biological resources and research for the exercise of ABS activities.

The guidelines strengthen state sovereignty over in situ biological resources and genetic resources and the constituent elements of biodiversity preserved outside their natural environment, the role of the state in ensuring a secure access equitable to any natural or legal person as well as the preservation and sharing of the benefits derived from their use. They clarify the ownership of traditional knowledge of indigenous communities and the need to respect and value the positive cultural rules of local communities or the community Biocultural protocols (BCPs). These guidelines also clarify the conditions for access to genetic resources, plant genetic resources for food and agriculture and associated traditional knowledge.

Thus, the procedures for applying for access permits, prior informed consent, mutually agreed terms and restrictions, the mechanism for implementation, monitoring and compliance have been clarified.

Legal framework for ABS implementation

Benin adopted Decree No. 2018-405 of 07/09/18 adopting the national guidelines for access and benefit-sharing derived from the use of genetic resources and associated traditional knowledge in the Republic of Benin. The decree is a follow-up to the establishment of an ABS committee of focal points of nine ministries and the development of the ABS national strategy. A strategy for the enhancement of genetic resources is being developed with the researchers, the tradi-therapists, the National Directorate of Scientific and Technological research. The decree adopted in the Council of Ministers does not suspend sectoral permits issued prior to its adoption. The collection permits in the classified forest area, in the waters, in the protected area of the state, and other genetic resources remain valid.

Institutional framework for ABS implementation

Prior to the entry into force of the Nagoya Protocol, access to genetic resources was regulated by various legislation and regulations. Two institutions regulate access to genetic resources. The ministry in charge of farming of livestock and fisheries for animal husbandry resources, fisheries resources. The Ministry of Environment gives access to the resources of the classified forests and the protected domain of the state.

With the adoption and implementation of the Nagoya Protocol, Benin has made the option of a funnel system (see figure above). All access requests are now forwarded to the national focal point, which is based on an ad hoc committee that reviews and validates applications. This committee is made up of the national focal point of the Nagoya Protocol, the focal point of the ITPGRFA, of resource persons and scientists familiar with the state of the resources in the country.

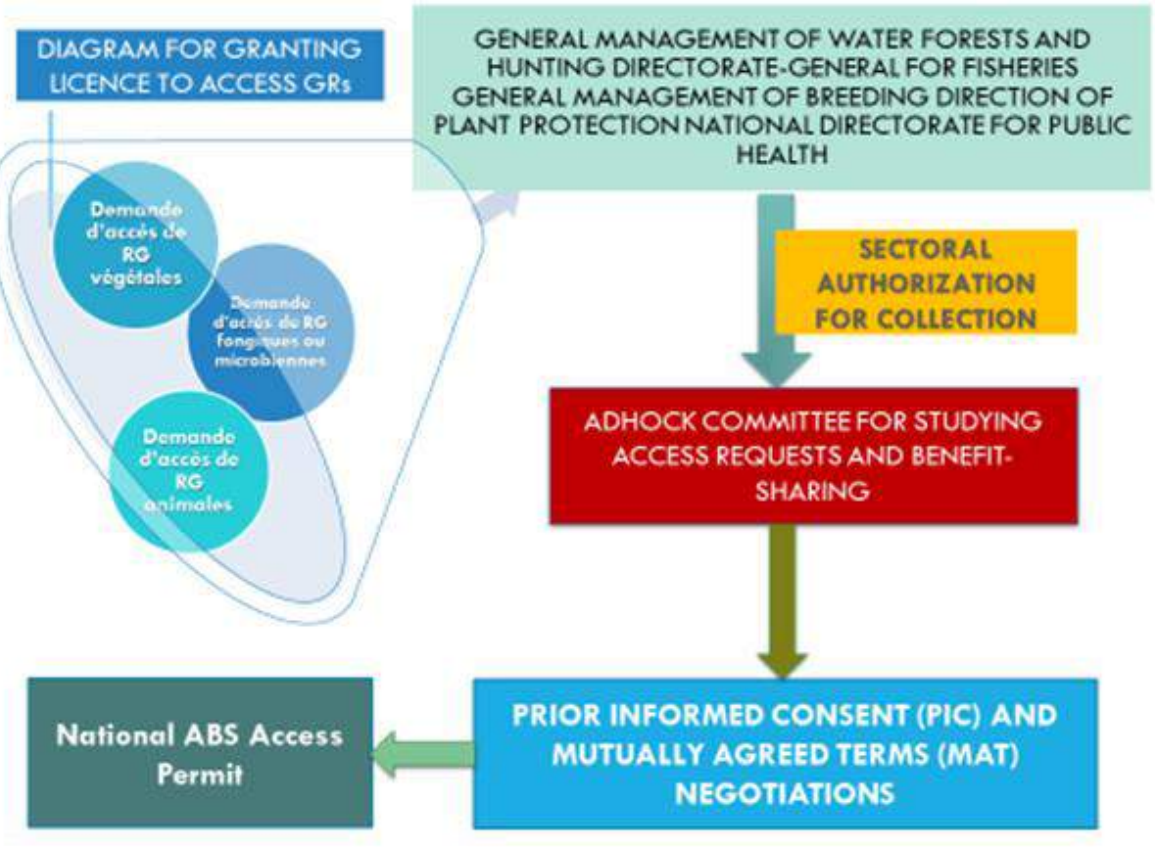


Fig. 29: Flow Chart Benin

During the transitional period, the national focal Point shall be the competent national authority issuing the PIC and the MATon the basis of the consents obtained from local suppliersThe publishing authority has been designated and regularly updates all documents (decree, ABS permit, implementation report etc...) for the implementation of the Protocol at national level.

Steps to access genetic resources and associated traditional knowledge

- Is there a difference between access for commercial and non-commercial purposes?

The access procedure is the same for non-commercial research needs and business needs (cosmetics, food, etc...). Access is subject to the obtaining of the PIC and the negotiation of a MAT. The clauses of renegotiation with the supplier are introduced in the signed MAT in case the research leads to commercial applications.

- Step-by-step procedures and timelines for access to genetic resources / associated traditional knowledge

Making contact and asking for the access procedure

The user sends a Letter to the ABS NFP informing him of his commercial interest or not for one or more species/GR and/or aTK and requests the procedure to be followed.

The NFP informs him of the existing procedure and sends him the forms of relevant documents ABS of Benin (basis: national guidelines) and information on other permits to obtain (CITES, phytosanitary certificate etc.) as appropriate.

He offered to draft the research MAT

Request for access to the research phase

The user fills in the application form indicating the objectives of the research, quantity of material etc.) and sends it to the NFP.

The user drafts (without having to negotiate) the research MAT. Justification: At this stage of the R&D the company is in an initial exploratory phase to determine whether it will undertake further analysis.

It invests little and there are few benefits to share. The idea is to propose a simple and easy procedure to collect more tangible benefits in a second time.

In the case of GR in the list in Schedule 1 of the ITPGRAA, the SMTA is signed between the supplier and the beneficiary.

Draft and negotiation of research MAT

The user sends the completed form to the NFP as well as a first draft of the research MAT:

Scope and objectives of the research

Price for the resource (samples)

Non-monetary benefits to be shared during the research phase (e.g. sharing of research results, joint publications, collaboration with a university or research centre in Benin....)

Confidentiality and intellectual property clauses

Obligation to renegotiate the MAT and obtain the PIC prior to the marketing phase.

In the case of the GRof the ITPGRFA refer to the SML of the Treaty.

Grant of PIC/access permit based on research MAT

After concluding the negotiations, MAT will be signed (electronic) between user and supplier. The user formally transmits the MAT to the NFP and receives the PIC.

The National Focal Point grants the PIC on the basis of the MAT negotiated in a permit.

The NFP informs/sends the completed and signed documents (PIC, MAT, licence and SMTA) to the relevant international partner structure for follow-up.

Under ABS-CH, the international system generates the internationally recognized permit and sends it to the national competent authority for further processing.

Later: PIC & MAT for the marketing phase

In the case of a marketing phase, the user informs the NFP of the results of the research. In case of interest in a marketing, the user contacts the NFP and begins the ABS commercial procedure for the marketing phase.

At this stage the benefits will be well known. The company will better know what it is going to be produced and can better estimate the potential monetary benefits.There will already be a confidential relationship with the company.

15.2 Questions and Answers

The following is a summary of key questions raised and issues discussed in plenary:

- Benin has created an Ad Hoc Committee where access requests are studied. This Ad Hoc Committee is composed of the ABS NFP, the NFP for ITPGRFA, scientists, representatives from the Ministries of Justice, Health and Fisheries as well as the National Agency for Intellectual Property.
- Benin faces several challenges: (1) there is a need for more capacity building for lawyers, the national IP agency and other stakeholders. (2) Benin needs to address the issue of management of transboundary GR (the neighboring countries Togo and Nigeria possess the same biodiversity, but do not have national ABS regulations in place). (3) There are no penalties foreseen in the interim measure.
- Benin has around 30 access requests only for research purposes. Benin has received two or three commercial access requests. The access demand form for commercial and non-commercial purposes is the same but there are two different contract templates (for commercial and non-commercial purposes).
- So far Benin has no administrative access fees because they are not yet specified in Benin's interim ABS measure. In the future it is planned to establish administrative fees through the implementing regulations. The Ad Hoc Committee, which is responsible for assessing access requests, currently functions without external support. The administrative fees would allow the Ad Hoc Committee to also function independently in the future.
- If a GR is accessed from a local community, the applicant needs to have the approval of the local community first.
- There is a set of GR that fall under the competence of the Ministry of Agriculture. However, Benin has a one-stop shop procedure. The ABS NFP is the point of access for the applicant for all kinds of resources.
- Benin fears that research results that are being published would fall in the public domain and the protection of TK would therefore become too difficult. However, the denial of access in such cases would stifle research running counter to the objectives of the Nagoya Protocol.

15.3 **Access Profile**

Tab. 21: Access Profile Benin

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	Yes	October 10, 2014	
Signatory	Yes	October 28, 2011	
NFP (National Focal Point)	Mr. Melkior Ogouwole Kouchade		
Contact NFP	kmelkior@yahoo.fr kouchade.melkior@gmail.com skype: Kouchade.melkior +229 972 62757 / 95053102		
CNA (Competent National Authority)	Forests, waters and hunting national directorate		
Contact CNA	kmelkior@yahoo.fr kouchade.melkior@gmail.com skype: Kouchade.melkior +229 972 62757 / 95053102		
CNA Deputy	No		
Contact CNA Deputy	No		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	Not applicable	Pilot experience in two munipalicities. Set up biodiversity register, designation of local authority for ABS, set up of communities ABS protocol.	
ABS law	Yes	Transitional decree set up since 15/03/2017	
Specific access regulation	Yes	There are specific access regulations in forest, fisheries and animal sectors.	

Criteria	Acquired information	Comments	Source
Specific access procedures (law or any defined process) for non-commercial use	Yes	Law No. 93-009 of 02 July 1993 relating to the forest, No. 2002-16 of 18 October 2004 relating to fauna; No 2014-19 of 07 August 2014 relating to fisheries	
English translation for users available	No		
Visualization of ABS procedure	Yes	Described in the transitional decree	
Information on access procedure / regulations accessible through web-link	Not yet	In progress through CBD CHM for Benin and ABS-CH	
Access request form	Yes	Available in the transitional decree adopted in 15/03/2017 annex2	
Specific access demand form for non-commercial purposes	No	Available in the transitional decree adopted in 15/03/2017 annex3 One access demand form but two different contract templates (commercial and non-commercial).	
Online application system	No		
Compulsory documents for access demand application	Yes	Available in the transitional decree adopted in 15/03/2017	
Submission of access application at	Name of institution	Forests, waters and hunting national directorate (The NFP is the contact person)	
Access fees	No	Depending on the resource's owner a prize for access could be negotiated. But there are no administrative fees in general yet. An administrative access fee is foreseen in future implementation regulations associated to the interim ABS Decree.	

Criteria	Acquired information	Comments	Source
Other permits prerequisite to obtain ABS permit	Yes	Depends on the sector (forest, fisheries, fauna, health ...) of the genetic resource you need. You have to ask for a collection authorisation at the respective directorate.	
IRCC (Internationally Recognised Certificate of Compliance)	No		
Have ABS permit(s) been issued in the country?	In progress	We have finalised the process of 15 access requests and the permit will be posted soon on the ABSCH.	
ABS permit(s) issued by	Name of institution	Forests, waters and hunting national directorate (For the interim measure period)	
Average timeline (from access demand to permit)	Timeline defined	60 days Since the acceptance of the access demand	
MAT(s) signed	Yes	For 15 access demand for research purposes	
MAT(s) to be signed with	Name of entity	Forests, waters and hunting national directorate (Signed by the NFP)	
Standard MAT clauses	Yes	Included in the contract signed with the users	
PIC(s) granted	Yes	For 15 access demand for research purposes	
PIC(s) to be granted by	Name of entity	NFP	

15.4 **Access Scenario Discussion**

Tab. 22: Access Scenario Discussion Benin

Case	**Parameter of the case**	
A university researcher from an EU member state informs the ABS authority in your country about his intention to interview members of a local community, which is known for its TK on the use of a plant extract against malaria. His intention is to know more about the extraction methods of traditional healers. He will collect the plants on the municipal land of the community; test the traditional extracts on their effectiveness against the parasite back in the EU and plans to publish the results in an international journal.	**user**	researcher from university
	commercial or non-commercial intent	non-commercial
	is the user from a party	yes
	provider in country	local community
	other actors involved	none
	IPLCs involved	yes
	aTK	yes
	location of excess	municipal land of the community / in situ

The solution to the access scenario was not available at editorial deadline.

16 Peer to Peer Exchange

In the peer-to-peer exchange that took place on the evening of the third day, participants were invited to discuss ABS topics of special interest in more detail. The following topics were proposed and discussed in three groups:

- Harmonised terminology
- CNA cooperation
- The ABS-CH mechanism

The first group discussed the need for harmonised terminology, in particular with respect to the terms “checkpoint” and “PIC”. The group presented its results as follows:

With respect to the term “checkpoint”:

- Recommendation of the participants of the ABS Dialogue 2018 that this term needs to be discussed so that countries may have a clearer understanding. Presently, some countries are using the term checkpoint to include unofficial internal access checkpoints, which is not the intended definition of checkpoint as appears in Article 17 of the Protocol.
- We are proposing that we leave the term checkpoint as it appears in Article 17 of the Nagoya Protocol and propose that unofficial internal access checkpoints be called “domestic checkpoints”.

With respect to the term “PIC”:

- This is an awareness raising issue. There are a broad range of interpretations of what PIC can entail, e.g. consent of IPLCs, permits, framework contracts, processes, etc, all of which are valid. But it is important to understand what PIC means for a given country.
- We would like to remind countries that according to Article 6, Section 1 of the Nagoya Protocol: “…access to GR… shall be subject to PIC of the party providing such resources…”. This means that countries not requiring PIC would grant free access to their GR.
- We would like to propose that countries clarify “How and in what form PIC is obtained” and publish this information on the ABS-CH.

In the subsequent discussion, it was pointed out that the term “domestic checkpoint” may be confusing for those who did not follow the Vilm discussions. Some proposed to use the term “provider country checkpoint” since the checkpoint under Article 17 is a user country checkpoint. However, this idea was eventually rejected because under the Nagoya Protocol all countries are considered user and provider countries and all countries are obliged to set up checkpoints under the Nagoya Protocol. Another proposition was the following: “checkpoint dealing with domestic GR” versus “checkpoint dealing with international GR”. These terms are also not ideal because some countries (e.g. Bhutan) only have one checkpoint which checks both domestic and international GR. Participants agreed that a new term needs to be found in order to avoid the false use of the term checkpoint.

“PIC” is also understood in different ways depending on the country. Some refer to PIC as a process. In many African countries, PIC refers to receiving consent from the relevant com-

munity. The varying use of the term makes it challenging not only for users but also for the underlying authority that is checking the user. It may be best to use clear and simple language by using terms such as “authorization” to explain the specific ABS procedure instead of using the terms of the CBD and / or the NP (“PIC”, “MAT”, etc.). What could make things easier, is the new procedure form for the ABS-CH that the SBCD is currently preparing, the so-called “common format”. Its aim is to clearly explain the ABS procedure of a given country.

The second group focused on the topic “CNA cooperation” in the context of ABS implementation. The following key points were made:

- CNA cooperation is crucial to further advance the implementation of the Nagoya Protocol. Collaboration needs to be strengthened at regional level (e.g. expert meetings in Brussels) and bilateral level.
- It is important to develop different fora for CNA cooperation. As a first step, a side event could be organized at COP 14 / MOP 3 to inform other CNAs about activities that are already taking place and to identify what levels of CNA cooperation are desired (“CNA Day”). Ideally, this should be a multiregional event organized in cooperation with the CBD Secretariat.
- At the moment, CNA cooperation is ad hoc and mostly occurs on a bilateral basis, but it would be helpful to have a clear framework. Good collaboration already exists in the CITES context. ABS CNAs also need a possibility to discuss (“CNA Forum”). It would be useful to look at the experiences of other multilateral environmental agreements to see what has and what has not worked well in this regard.
- More trust needs to be built in order to make ABS work. Events like the Vilm ABS dialogues provide excellent opportunities to learn from other countries implementing the Nagoya Protocol and to work on concrete solutions by looking at best practices and challenges. Bilateral discussions taking place at such dialogues also contribute to building trust.

The third group discussed the importance of the ABS Clearing-House mechanism. The key messages are summarized below:

- It is important to publish relevant information on the ABSCH.
- Provider countries should attempt to make it easy for users by leaving their national, legal perspective and the complexity of the respective national ABS system by using clear Nagoya Protocol language. If the authority in a country performs the function of a CNA, the SCBD advises using this term even if the respective authority has a different name.
- Efforts should be put into the monitoring of GR.
- Aside from key documents such as PIC, MAT, permit that are to be uploaded in the ABSCH, it is also helpful to include explanatory information on the respective ABS system in the Clearing-House.
- If your country is developing or about to develop an online system, they should get in touch with the IT staff of the SCBD in order to link the national system with the ABSCH with a view to avoid the need for updating two websites at the same time.

- The SCBD is available for support. All ABS actors (users, providers, regulators, etc.) should make use of the ABSCH mechanism. The SCBD has developed a “training website” on the ABSCH to help users and providers get acquainted with this mechanism.

17 Overall Discussion

In an overall discussion, moderated by Peter Schauerte, key access questions from this meeting were identified. These can be summarized as follows:

- The legal framework is the basis for any ABS system.
- There exists a diversity of access rules (one-phased versus two-phased system; distinction between access for commercial or non-commercial purposes; one CNA versus several CNAs; including or excluding commodities; specialized measures for pathogens).
- In most countries a local counterpart is a prerequisite for foreigners wishing to undertake research on GR and/or aTK in the provider country.
- Access and benefit-sharing need to be linked. Benefit-sharing models can differ depending on the national context (fixed sums, upfront payment, etc.). Some countries have set up national benefit-sharing funds.

Peter Schauerte informed participants that the ABS Initiative in collaboration with several ABS experts is currently working on a paper showing a variety of different ABS implementation options. This paper may serve as a basis for informed decision-making and may be shared with interested participants once available.

This session also focused on the importance of communication and exchange with users. A number of key issues were raised, including the following:

- The ABS-CH is a key instrument aimed at providing transparency on procedures for access, and for monitoring the utilisation of GR along the value chain. Participants were encouraged to make better use of this mechanism.
- Visualizations of ABS procedures (e.g. flowcharts illustrating different access procedures) are a very practical help for users.
- Continuous information exchange on ABS is crucial. One way of information sharing is to upload relevant documents onto the ABS-CH. These documents should ideally be translated into English before being posted on the ABSCH.
- CNAs in user and provider countries need to exchange information and cooperate on cases of non-compliance.
- Online systems for sharing information and permitting processes play a key role in ABS implementation. Harmonization of national online systems with the ABSCH is to be considered.

18 Way Forward and Closure

Before the ABS Dialogue was brought to a close, final remarks were held by the SCBD and BfN.

Beatriz Gomez (SCBD) thanked everyone for their active engagement in discussions and encouraged participants to make relevant information available on the ABSCH. She highlighted that the Secretariat offers tailored support for countries struggling with providing relevant information on the ABSCH.

Thomas Greiber (BfN) thanked all participants for sharing their experiences and the facilitators of GeoMedia for organizing this event. The ABS dialogue allowed the advanced countries in ABS implementation to exchange and discuss their experiences with setting up and running an ABS system. The outcomes of the Vilm dialogues 2017 and 2018 will be shared and discussed at a side event which will take place at the Fourteenth meeting of the Conference of the Parties to the CBD in November this year in Sharm El-Sheikh, Egypt.

Overall, the interactive format of the dialogue and the active involvement of the participants contributed to the success of the meeting and provided a good basis for fruitful and rich discussions to advance the implementation of the Nagoya Protocol.

Annex

Pictures of the Workshop and the Isle of Vilm

Agenda

List of Participants

Pictures of the Workshop and the Isle of Vilm



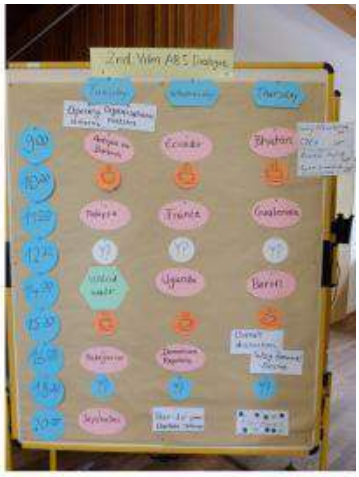





Welcome

Welcome


Welcome


2nd Wien ARE Dialogue









Welcome
























Agenda

2nd Vilm ABS Dialogue – Informing about Domestic Measures for Access to Genetic Resources

September 10 - 14, 2018

at the International Academy for Nature Conservation,
Isle of Vilm, Germany

on behalf of the Nagoya CNA-Unit
of the German Federal Agency for Nature Conservation (BfN)

Background

After entry into force of the Nagoya Protocol and the corresponding Regulation (EU) No 511/2014, European users of genetic resources (GR) are required to "exercise due diligence" to ensure that they have acquired GR or associated traditional knowledge in accordance with the national access procedures of the respective provider country. In Germany, as in other EU member states, "competent national authorities" (CNAs) for ABS are in the course of formation and a first meeting of European CNAs already took place in March 2017 on Vilm-Island. One of the discussed implementation challenges was the **availability of transparent and reliable national access regulations** in provider countries. CNAs, as the German Nagoya CNA-Unit, are repeatedly being asked for information and advice in this regard. But the ABS Clearing House, designed as the key tool for information exchange aiming at enhancing legal certainty, clarity, and transparency on procedures for access to GR, is not yet sufficiently populated and thus does not allow users to gather the relevant information for the vast majority of countries.

To foster the process of implementing the Nagoya Protocol, the Nagoya CNA – Unit of the German Federal Agency for Nature Conservation (BfN) is organizing a series of two international ABS dialogues (August 2017 and September 2018) at the International Academy for Nature Conservation on the Baltic Sea Isle of Vilm, Germany. The dialogues are intended to provide an opportunity to identify and present best-practices on available, clear and transparent access regulations with representatives of CNAs/NFPs of provider countries. In this sense, the objective of the meetings is not to promote facilitated access, but rather to secure transparency, in order to allow users of GR to be better informed by European CNA's towards countries that have structured, clear, and transparent access measures in place.

To identify countries that already have clear and structured transparent access procedures in place, BfN commissioned an overview study to guide the selection and invitation of approx. 10 countries (as in 2017). At the meeting, two representatives of each country will be asked to present their respective access regulations and procedures. It is further foreseen to compile a summary table of the presented access procedures which will feed into a planned publication in the conference volume (BfN-Script). The respective report of the first dialogue in 2017 can be downloaded here.

AGENDA

Monday, 10.09.2018

Arrival of the participants on the island of Vilm

18.30 *Dinner*

20.30 Welcome and Brief Introduction to the Meeting

MS. UTE FEIT, GERMAN COMPETENT NATIONAL AUTHORITY FOR THE NAGOYA PROTOCOL (BFN)

PARTICIPANTS INTRODUCTION - ALL

21.30 *Informal get-together*

Tuesday, 11.09.2018

07.30 *Breakfast*

08.30 **Opening Remarks: The Journey Implementing the Nagoya Protocol**
MR. THOMAS GREIBER, GERMAN COMPETENT NATIONAL AUTHORITY FOR THE NAGOYA PROTOCOL (BFN)
MS. BEATRIZ GOMEZ, PROGRAMME OFFICER ON ABS, SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY
MS. ALICJA KOZLOWSKA, ABS NFP, ABS-CH INFORMAL ADVISORY COMMITTEE
EU COMMISSION

08.55 **Organisational matters**
MR. PETER SCHAUERTE, GEOMEDIA GMBH (APPROX. 5 MIN.)

09.00 **Access Procedures of Antigua and Barbuda**
Ms. Helena Brown, Technical Coordinator, Department of Environment, Ministry of Health, Wellness and the Environment
Ms. Nneka Nicholas, Technical Officer / Legal Consultant, Department of the Environment, Ministry of Health, Wellness and the Environment

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)

- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

10.30 *Coffee / Tea*

11.00 **Access Procedures of Malaysia**
Ms. Siti Nurzaliana Mohd Safari, Assistant Secretary, Biodiversity and Forestry Management Division, Ministry of Water, Land and Natural Resources
Mr. Chitdrakantan Subramaniam, Principle Assistant Secretary, Biodiversity and Forestry Management Division, Ministry of Water, Land and Natural Resources

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

12.30 *Lunch*

14.00 **Guided Tour and Walk through the Nature Reserve of the Island of Vilm**
JUTTA STADLER, FEDERAL AGENCY FOR NATURE CONSERVATION (90 MIN.)

15.30 *Coffee/ Tea*

16.00 **Access Procedures of Madagascar**
Ms. Lolona Ramamonjisoa Ranaivoson, ABS National Focal Point, Ministry of Environment, Ecology and Forests
Ms. Rantonirina Rakotoaridera, ABS CNA Representative, Ministry of Environment, Ecology and Forests

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

18.30 *Dinner*

20.00 **Access Procedures of the Republic of Seychelles**
Mr. Denis Matatiken, ABS National Focal Point, Ministry of Environment, Energy and Climate Change
Ms. Marie-May Muzungaile, Director General, Biodiversity Conservation and Management Division, Ministry of Environment, Energy and Climate Change

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

Wednesday, 12.09.2018

07.30 Breakfast

09.00 **Access Procedures of Ecuador**
Mr. Ricardo Andrade, Genetic Resources Analyst, National Directorate of Biodiversity, Ministry of the Environment
Mr. Pablo Cueva, Secretariat of Higher Education, Science, Technology and Innovation (SENESCYT)

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

10.30 Coffee / Tea

11.00 **Access Procedures of France**
Mr. Guillaume Faure, Deputy Head of Supervision of Impacts Office, Water and Biodiversity Directorate, Ministry for an Ecological and Solidary Transition

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

12.30 Lunch

14.00 **Access Procedures of Uganda**
Mr. Akampurira Innocent Rolds, ABS Competent Authority, Uganda National Council for Science and Technology

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

15.30 *Coffee/ Tea*

16.00 **Access Procedures of the Dominican Republic**
Ms. Luisa Arelis Castillo Bautista de Espinal, National Office of Industrial Property (ONAPI)
Ms. Lida Sibilio, Head of the Collection Division, Legal Direction of the Ministry of Environment and Natural Resources of the Dominican Republic

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

18.30 *Dinner*

20.00 Evening session:

Peer-to-peer thematic exchange (voluntary)

Thursday, 13.09.2018

07.30 *Breakfast*

09.00 **Access Procedures of Bhutan**
Mr. Chencho Dorji, Head of Bioprospecting and ABS Program / ABS National Focal Point, National Biodiversity Center, Ministry of Agriculture and Forests
Ms. Nima Om, Senior Legal Officer, Ministry of Agriculture and Forests

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

10.30 *Coffee / Tea*

11.00 **Access Procedures of Guatemala**
Ms. Karen Jeanneth de la Cruz Orellana, Notary / Legal

Adviser, Legal Affairs Unit, National Council of Protected Areas (CONAP)

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

12.30 Lunch

14.00 **Access Procedures of Benin**

Mr. Melkior Kouchade, ABS National Focal Point, Ministry of the Environment and Sustainable Development
Mr. Mensah Bienvenu Célestin Bossou, Executive Director, NGO CeSaReN

- COUNTRY PRESENTATION (APPROX. 30 MIN.)
- QUESTIONS AND ANSWERS (APPROX. 20 MIN.)
- ACCESS PROFILE (APPROX. 20 MIN.)
- ACCESS SCENARIO DISCUSSION (APPROX. 20 MIN.)

15.30 Coffee / Tea

16.00 **Overall discussion**

- KEY ACCESS QUESTIONS AND OPTIONS FOR ADDRESSING THEM (30 MIN.)
- COMMUNICATION AND EXCHANGE WITH USERS (15 MIN.)

16.45 **Way forward and Closure**

- PUBLICATION (5 MIN.)
- FURTHER CNA COOPERATION (10 MIN.)
- SCBD WAY FORWARD (10 MIN.)
- Closure (10 min.)

17.30 Reception / Dinner and Farewell

CULTURAL GET-TOGETHER (ANY KIND OF CONTRIBUTION TO THIS EVENING, E.G. SONGS, TRADITIONAL DANCES, PRESENTING TRADITIONAL FOOD, IS GREATLY APPRECIATED). THERE IS ALSO A PIANO IN THE CONFERENCE ROOM.

Friday, 14.09.2018

07.30 Breakfast and Departure

The Isle of Vilm, 94 hectares in area, is a beautiful nature paradise, a Baltic Sea coast treasure. The island's natural beauty has long fascinated people. The first steps to protect its ancient forest from logging were taken back in 1812. In 1936, the Isle of Vilm was set aside as a nature reserve. Since 1990, it has been one of the core areas of the Southeast-Rügen Biosphere Reserve.

List of participants

2nd Vilm ABS Dialogue – Informing about Domestic Measures for Access to Genetic Resources

10 to 14 September 2018

held at the German Federal Agency for Nature Conservation – International Academy for Nature Conservation Isle of Vilm

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