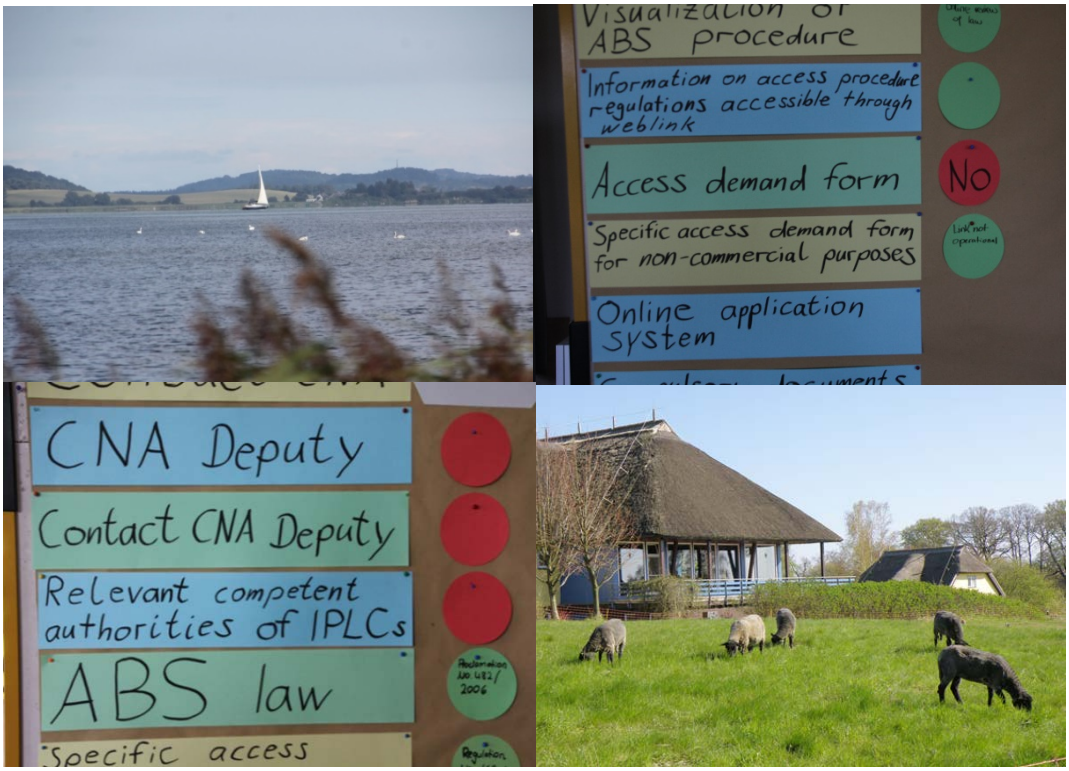
**Suhel al-Janabi, Ute Feit, Eva Fenster,
Thomas Greiber and Peter Schauerte (Eds.)**

Vilm ABS Dialogue 2017 – Informing about Domestic Measures for Access to Genetic Resources

Final Report

Presenting Countries: Australia, Brazil, Costa Rica, Ethiopia, India, Kenya, Mexico, Peru, Philippines, South Africa and Viet Nam



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Vilm ABS Dialogue 2017 – 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, 27 - 31 August 2017

Presenting Countries: Australia, Brazil, Costa Rica, Ethiopia, India, Kenya, Mexico, Peru, Philippines, South Africa and Viet Nam

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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
BMUB	Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety
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 Certificates of Compliance
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
NFP	National Focal Point
PIC	Prior Informed Consent
RD	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 are required to "exercise due diligence" to ensure that they have acquired genetic resources 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 first meetings of European CNAs already took place.[1] 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 of the Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN), are repeatedly being asked for information and advice in this regard. But the international 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 genetic resources, is not yet sufficiently populated and thus does not allow users to gather the relevant information for the vast majority of countries.

To counter such legal uncertainties, the Nagoya CNA-Unit of the BfN organized an international exchange of information and experience, the “Vilm ABS Dialogue – Informing about Domestic Measures for Access to Genetic Resources” in August 2017 at the BfN-branch office on Vilm Island. The conference gave an opportunity to identify and present best-practices on available, clear and transparent access regulations with representatives of CNAs/National Focal Points (NFPs) of provider countries. In this sense, the objective of the meeting was not to promote facilitated access, but rather to secure transparency, in order to allow users of genetic resources 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 approximately 10 countries for the first ABS dialogue.

First, an access profile template for summarizing the most relevant information on the respective ABS systems per country was developed. 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 first scan of the ABS-CH revealed that currently (as of July 2017) 47 countries have posted legislative measures on the ABS-CH, out of which 32 are countries from the European Union (EU) or other countries being typically regarded as user countries, and thus not of particular interest for the dialogue. It has to be stated that many of the posted legislative measures do neither define an overall ABS system nor specific access procedures, but are legislative measures for e.g. the ratification of or the accession to the Nagoya Protocol. The first scan of the ABS-CH thus revealed 15 countries as potential candidates for the first dialogue. It turned out that these 15 countries have a total of 64 legislative ABS measures posted on the ABS-CH. Nevertheless the investigation revealed that out of these 64 measures, more than half (35) do not contain any information on the access procedures of the respective

[1] A first meeting of European CNAs was held in March 2017 on behalf of the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) at its branch office on Vilm-Island, followed by a second meeting in September 2017 in Brussels.

countries. Five countries do have at least one Internationally Recognized Certificate of Compliance (IRCC) posted on the ABS-CH, which is a clear indication that the ABS system is operational. Further research carried out (Google, ECOLEX and network of ABS experts) showed additional eight countries that are rather advanced concerning their access measures, but that do not have their measures posted on the ABS-CH yet. The combined research thus led to a list of 23 countries whose access profiles were first filled out by the researchers and then sent to the NFPs of the individual countries for revision and correction if necessary.

Based on the results of the above-mentioned study, the following ten countries, mostly ABS NFPs and representatives of the CNAs, accepted to present their respective access procedures during the ABS dialogue on the isle of Vilm (in alphabetical order): Australia, Brazil, Costa Rica, Ethiopia, India, Kenya, Peru, Philippines, South Africa and Viet Nam. Completed by representatives of Mexico as the current presidency of the CBD Conference of the Parties (COP), of EU member states CNAs, the European Commission, the Secretariat of the Convention on Biological Diversity (SCBD) and of the ABS Capacity Development Initiative, the ABS Dialogue brought together around 40 participants from 19 countries in America, Australia, Asia and Europe. For further details, a list of participants is attached in the annex.

It can be concluded from the meeting and its underlying scoping study that almost three years after the entry into force of the Nagoya Protocol, the number of countries with functioning, clear and transparent access measures in place is still very limited. The ABS Dialogue 2017 thus came at the right time as it allowed advanced countries of ABS implementation to discuss their experiences with setting up and running an ABS system. Other provider countries which are currently developing access processes will benefit from these results. Furthermore, one essential goal of the conference was the joint creation of the so-called access profiles which will be published in the following sections. These will now serve the users as transparent instructions for legally compliant access to the resources in the respective countries.

Finally, it should be noted the ABS Dialogue 2017 can only be a first step towards ABS transparency and legal certainty. Consequently, it is planned to organize a second Vilm Dialogue of the same kind in 2018 (September 10-14) which will give 10 more countries the opportunity to present their current access conditions to their genetic resources.

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.

2 Opening Remarks: The Journey Implementing the Nagoya Protocol

Opening remarks at the ABS Dialogue were held by the German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB), the Secretariat of the Convention on Biological Diversity (SCBD) and the European Commission (EC).

They were preceded by a warm welcome on the first evening through representatives of the initiating institution of the conference, Mr. Thomas Greiber, Head of the German Competent National Authority for the Nagoya Protocol – which forms a part of the BfN – and his colleague Mrs. Ute Feit. The latter 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 further a deeper and better communication and cooperation beween CNAs of provider and user countries. Mrs. Feit introduced and thanked Mr. Suhel Al Janabi, Executive Director of GeoMedia GmbH and his team for their organizational support during the event.

On behalf of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, Dr. Stefan Lütkes, Head of Division Law of Nature and Landscape Conservation welcomed participants to the ABS Dialogue 2017. In his opening speech, Dr. Lütkes referred to the history of origins of the Nagoya Protocol, highlighting that Germany has been a critical and constructive partner for the implementation of the Protocol from the beginning. He further informed participants that the objective of this dialogue is to discuss practical implications of the Nagoya Protocol implementation and that mutual trust lies at the core of successful ABS implementation.

Valerie Normand, Senior Programme Officer for ABS at the SCBD provided participants with an overview of the status of Nagoya Protocol implementation, the UN Biodiversity Conference and key issues for 2017-2018 as well as SCBD capacity-building activities supporting implementation of the Nagoya Protocol.

Alicja Kozlowska, Policy Officer for ABS under the Nagoya Protocol at the European Commission thanked the German authorities for organising this meeting and reported on the developments at the level of the European Union, focusing on EU Regulation No. 511/2014 and the users' due diligence obligation.

3 Agenda, Objective and Work Flow of the Workshop

Mr. Suhel al-Janabi, gave participants a brief overview of the agenda (see annex VI - XXI). 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 genetic resources. This will especially allow European CNAs to inform and guide users of genetic resources 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 30 minutes were used for the presentation of the access procedures, including questions and answers. A second block of 30 minutes was used to introduce a fictional ABS case scenario and to project this scenario onto the respective ABS system (see annex XXII - XXXV). In the third and last block of 30 minutes, an access profile was filled in for each country, summarizing the key features of the respective ABS systems. On the third day and after all countries had discussed their access procedures, Mexico, in its special role as COP presidency, gave an overview of the current status of the ABS system in Mexico. An overall discussion then allowed identifying key access questions and options for addressing them and underligned the importance of flow charts as a graphic tool to illustrate different access procedures in an easy to understand manner. At last, the way forward was outlined and discussed with respect to this publication, options for further CNA cooperation, the second Vilm Dialogue and the activities foreseen by the SCBD.

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 genetic resources / associated traditional knowledge
- What is required to access genetic resources / associated traditional knowledge 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 genetic resources / associated traditional knowledge

5 Access Procedures of Viet Nam

Ms. Nguyen Dang Thu Cuc, Head of Division for Genetic Resources and Biosafety Management, Biodiversity Conservation Agency

Fig. 1: Ms. Nguyen Dang Thu Cuc

5.1 Country Presentation

Regulatory framework on Access to GRs and Benefit sharing from utilization of GRs in Vietnam

Vietnam has become a member to the Convention on Biological Diversity in 1994 and ratified the Nagoya Protocol in 2014. The first national regulations on Access to GRs and Benefit sharing from utilization of GRs (ABS) were conceptualized in the Law on Biodiversity (2008).

The new Decree no. 59/2017/ND-CP on management of access to and benefit sharing from utilization of Genetic Resources (GRs) has institutionalized provisions and obligations of the Nagoya Protocol into Vietnam context as a member nation. It also details regulations on ABS in the Biodiversity Law (2008) to keep up with the currently ongoing demands for GRs usage activities all over the world. Major contents of the Decree include:

- ABS activities principles (Article 4)
- Designation of the Ministry of Environmental and Natural Resources (MONRE) as National Focal Point to the Nagoya Protocol (Article 5)
- Identification of two national competent authorities including MONRE and Ministry of Agriculture and Rural Development (MARD) (Article 6), in which, MARD grants, renews or withdraws licenses to access genetic resources of agricultural crop varieties, livestock, aquatic species, and forest seedlings. MONRE is also responsible for the other genetic resources, including wild specimens.
- Identification of 3 groups of entities which must obtain the License to access to GRs (Article 7.1), including (1) Vietnamese organizations and individuals access GR for commercial purposes or for the development of commercial products; (2) Foreign individuals and organizations access genetic resources for any purpose; and (3) Domestic individuals and organizations wishing to take genetic resources out of

Vietnamese territory, unless Vietnamese students, doctoral students, or science and technology organizations who wish to transfer genetic resources out of the Vietnamese territory for study purposes or research for non-commercial purposes. Procedures to obtain the License (Article 8-14)

- Provisions on the contract (MAT) and License (PIC) (Article 15-18) and the Contract template (Form 3)
- Provisions on benefit-sharing (Article 21-23)

The main challenge during development of these regulations was how to make them implementable while simultaneously setting up a system that works for both regulators and users, and bring back benefits for providers. Secondly, traditional knowledge associated with GRs remains an issue not yet to be solved, further guidance needs be developed.

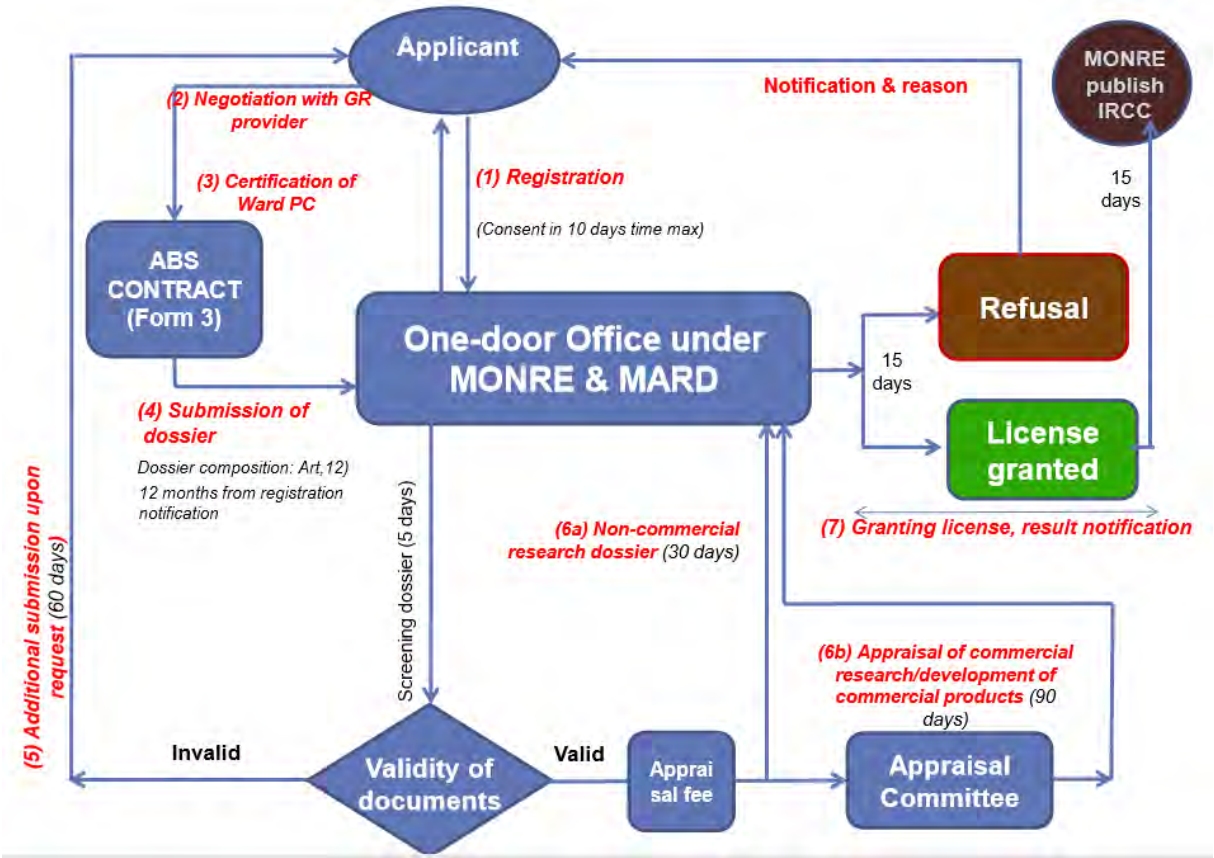

Fig. 2: Diagram for granting license to access GRs

5.2 Questions and Answers

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

How are users reacting to the situation now that ABS is being regulated in Viet Nam? Now that access to genetic resources is regulated in Viet Nam, foreign users seek information from Vietnamese national competent authorities on how to comply with ABS.

- Does Viet Nam have a single-window approach? In order to access genetic resources in Viet Nam, the user needs to register with the relevant national authority. There are

two CNAs in Viet Nam: 1) the Ministry of Agriculture and Rural Development (MARD), contact point of which is Department of Science, Technology and Environment and 2) the Ministry of Natural Resources and Environment (MONRE), the contact point of which is Biodiversity Conservation Agency. The former (MARD) is responsible for access of genetic resources of agricultural crop, livestock breeds, aquatic species and forest seedlings. The latter (MONRE) is responsible for access to all other genetic resources.

- Access requirements in Viet Nam distinguish between 1) individuals vs. organizations; 2) nationals vs. foreigners; 3) non-commercial vs. commercial purposes. For example, foreigners must provide a cooperation agreement with an organization in Viet Nam. National students and research institutions have a simplified procedure to obtain allowance to transfer genetic resources abroad. Further, there is a difference in the processing duration for non-commercial (30 days) and commercial purposes (90 days).
- The appraisal time (30 days for non-commercial research purposes / 90 days for commercial research or commercial product development purposes) is specified. Does Viet Nam have any appraisal fees? At the moment, no appraisal fees are applied. Further guidance on appraisal fees will be developed in the future.
- ABS contracts in Viet Nam are signed with the provider, but benefits are given to the government. Does the provider receive any benefits? Yes, if the provider is an institution for example it will receive 30% and the government receives 70% of monetary benefits. If the provider is a landowner, 50 % of the monetary benefits are given to the landowner, 50 % to the government. For traditional knowledge it may be different. In the recent Decree 59 dated 12 May 2017 traditional knowledge is not yet included. An under-Decree is being developed.
- The government seems to play a key role when it comes to monetary benefit-sharing. How is benefit-sharing defined? Benefit-sharing is very difficult to define. There is no benefit-sharing fund in Viet Nam. Monetary benefits are channeled to the State budget to prioritize biodiversity conservation activities.

5.3 **Access Profile**

Tab. 1: Access profile Viet Nam

Criteria	**Acquired information**	**Comments**	**Source**
Party Nagoya Protocol	Yes		ABS -CH only
Signatory	No		ABS -CH only
NFP (National Focal Point)	yes	The Ministry of Natural Resources and Environment	ABS -CH only
Contact NFP	hnhan@vea.gov.vn ho-angnhan.bca@gmail.com +Add: 10 Ton That Thuyet street, NamTu Liem district, Hanoi, Vietnam; Tel: +84 24 3795 6868 (ext. 3113)		ABS -CH only
CNA (Competent National Authority)	Yes	1. The Ministry of Natural Resources and Environment (MONRE) 2. The Ministry of Agriculture and Rural Development (MARD)	ABS -CH only
Contact CNA	vanphongcucbaoton@gmail.com, Add: 10 Ton That Thuyet street, NamTu Liem district, Hanoi, Vietnam; Tel: +84 24 3795 6868 (ext. 3117)		ABS -CH only
CNA Deputy	No		
Contact CNA Deputy	No		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	no information		
ABS law	Yes		ABS -CH only
Specific access regulation	yes	The Decree sets out 5-step process to access genetic resources: 1. register with CNA, 2. negotiate and sign contract with Provider, 3. request certification from Commune-level People's Committee, 4. submit dossier requesting access license to CNA, 5. provide any additional information to finalize dossier if requested by CNA.(Article 9-13)	Decree no.59/2017/ND-CP

Criteria	Acquired information	Comments	Source
Specific access procedures (law or any defined process) for non-commercial use	yes	only Vietnamese non-commercial research does not have to follow the access procedure; foreign non-commercial research has to follow access procedures; reduced appraisal time for non-commercial research	Decree no.59/2017/ ND-CP
English translation for users	yes	English	ABS -CH only
Visualization of ABS procedure	No	(being translated) not ready yet	ABS -CH only
Information on access procedure / regulations accessible through weblink	Yes	https://absch.cbd.int/database/record/ABSCH-MSR-VN-237595	ABS -CH only
Access demand form	yes	Sample form 02 Application for access to genetic resources under the Decree	Decree no.59/2017/ ND-CP
Specific access demand form for non-commercial purposes	No		Decree no.59/2017/ ND-CP
Online application system	no	in planning	Decree no.59/2017/ ND-CP
Compulsory documents for access demand application	yes	yes 1) registration (registration access form, legal status documents, cooperation agreement with Vietnamese research entity, registration authorization if applying as a group) 2) contract negotiation 3) communal people's committee certification 4) access demand form	Decree no.59/2017/ ND-CP
Submission of access application at	Yes	One-door office at the Ministry of Agriculture and Rural Development: for access to agricultural crop varieties, livestock breeds, aquatic species, and forest seedlings; One door Office at Ministry of Natural Resources and Environment: for access to all other cases (including medicinal plants, wild GR, etc.)	Decree no.59/2017/ ND-CP
Access fees	yes	yes, in preparation - fee is applied after acceptance of access dossier;	Decree no.59/2017/ ND-CP

Criteria	Acquired information	Comments	Source
Other permits prerequisite to obtain ABS permit	no information	In cases where the genetic resources are in the list of genetic resources limited for accession and utilization, written approval of the sectorial management Ministries and agencies is required (Article 12.1.c)	Decree no.59/2017/ ND-CP
IRCC (Internationally Recognised Certificate of Compliance)	no	MONRE shall be reponsible to publish any License to access to GRs (issued by MONRE or MARD) to the ABS CHM to be constituted as an IRCC (Art.24)	Decree no.59/2017/ ND-CP
Have ABS permit(s) been issued in the country?	No	No any ABS permit issued	
ABS permit(s) issued by	no information		
Average timeline (from access demand to permit)	timeline defined	Registration: 10 days Negotiation: up to 12 months Certification: 3 days Acceptance of access dossier: 5 days Finalization of access dossier: up to 60 days Appraisal of access dossier by appraisal committee: 90 days (for commercial research or; commercial product development purposes) and 30 days (for non-commercial research purposes) CNA decision on access: 15 days sum: 123 days for commercial research or; commercial product development purposes), 63 days (for non-commercial research purpose) and without counting the finalization that is done by the applicant	Decree no.59/2017/ ND-CP
MAT(s) signed	no information		
MAT(s) to be signed with	Name (s) of entity	GR holders	Biodiversity Law, Art.55
Standard MAT clauses	yes	Model contract with some clauses exists	Decree no.59/2017/ ND-CP
PIC(s) granted	no information		
PIC(s) to be granted by	Name (s) of entity		

6 Access Procedures of Ethiopia

Dr. Melesse Maryo, Director General of Ethiopian Biodiversity Institute (EBI);

Mr. Ashenafi Ayenew Hailu, Director, Genetic Resource Access and Benefit Sharing Directorate, Ethiopian Biodiversity Institute (EBI), ABS National Focal Point

Fig. 3: Dr. Melesse Maryo and Mr. Ashenafi Ayenew Hailu

6.1 Country Presentation

Ethiopia has ratified the Convention on Biological Diversity (CBD) and the Nagoya Protocol in 1994 and 2012 respectively. Ethiopia has also ratified the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) in 2003. Ethiopia has put in place both institutional and legal frameworks to implement the third objective of the CBD, i.e. to facilitate access and ensure fair and equitable benefit sharing. The Ethiopian ABS system also provides legal space for the implementation of the ITPGRFA special approach to ABS to PGRFA (MLS/SMTA).

The Ethiopian Biodiversity Institute (EBI) is a Competent National Authority (CNA), i.e. responsible for granting access. It is also the Focal Institute to the CBD and ITPGRFA and this helps for mutual supportive implementation of the bilateral ABS system established by CBD/NP and the multilateral ABS system established by ITPGRFA. To effectively implement ABS issues, EBI has established the Genetic Resource Access and Benefit Sharing Directorate as core process since 2010. The Directorate is mandated (authorized) to regulate genetic resources transfer (access to GRs/TK) and to ensure that the country and its communities get fair and equitable share of benefits arising from the utilization of their GRs/TK. The Directorate is also the focal point to the Nagoya Protocol / ABS.

Ethiopia has issued Access to Genetic Resources and Community Knowledge and Community Rights (ABS Law), Proclamation (No.482/2006) and Regulation (No.169/2009). The legislations focus on PIC, MAT, Multilateral System of Access and how to implement relevant activities. According to the Ethiopian ABS law, access means the collection, acquisition, transfer or use of genetic resources and/ or community knowledge. The law applies on access to genetic resources found in in-situ or ex-situ conditions and community knowledge. No person shall access GRs or community knowledge (CK) unless in possession of a written access permit granted by EBI based on PIC. No person shall export GRs out of Ethiopia

unless in possession of a permit granted by EBI.

Access to GRs shall be subject to the PIC of EBI and access to CK shall be subject to the PIC of the concerned local community. An access applicant who is a foreigner should present a letter from the competent authority of his national state or that of his domicile assuring that they will uphold and enforce the access obligations of the applicant.

Ethiopia has designated a publishing authority and published the ABS proclamation and regulation on the CBD-ABS-Clearing House (ABSCH) and information on ABS, MTA and assurance letter formats are available on the EBI website (www.ebi.gov.et).

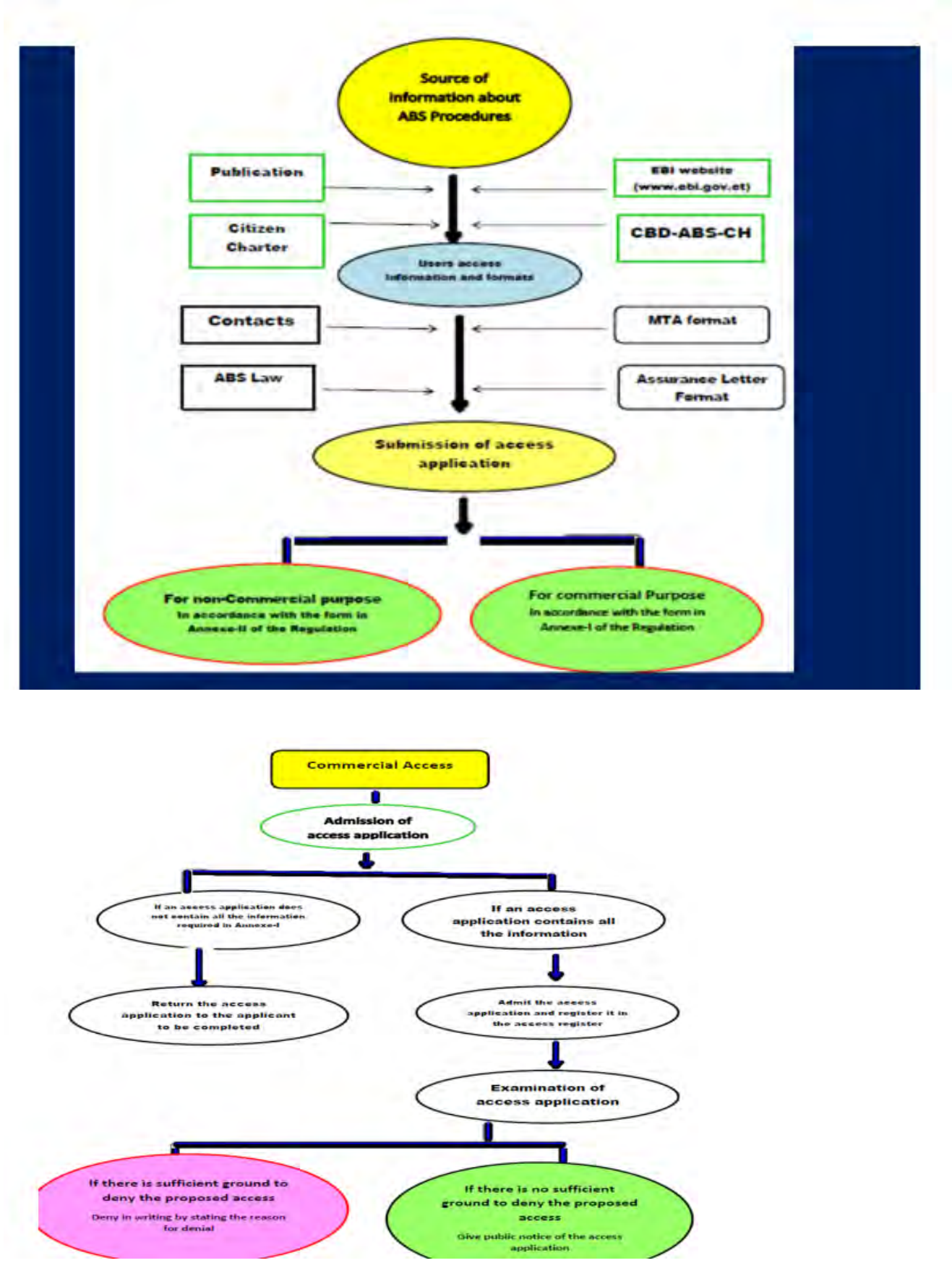

Fig. 5: Flow Chart Ethiopia 2

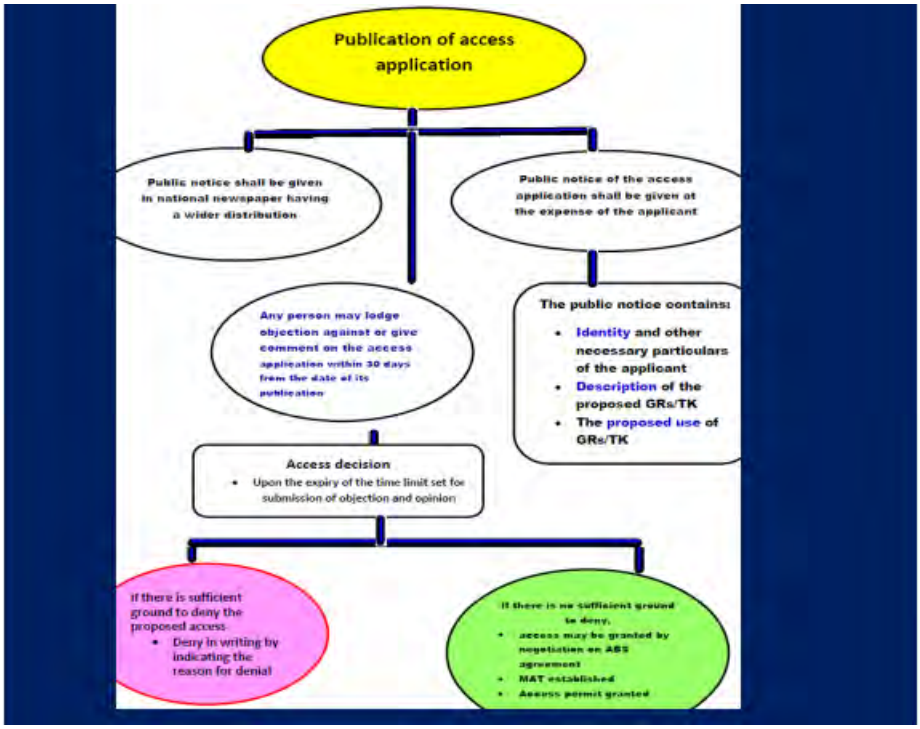

Fig. 6: Flow Chart Ethiopia 3

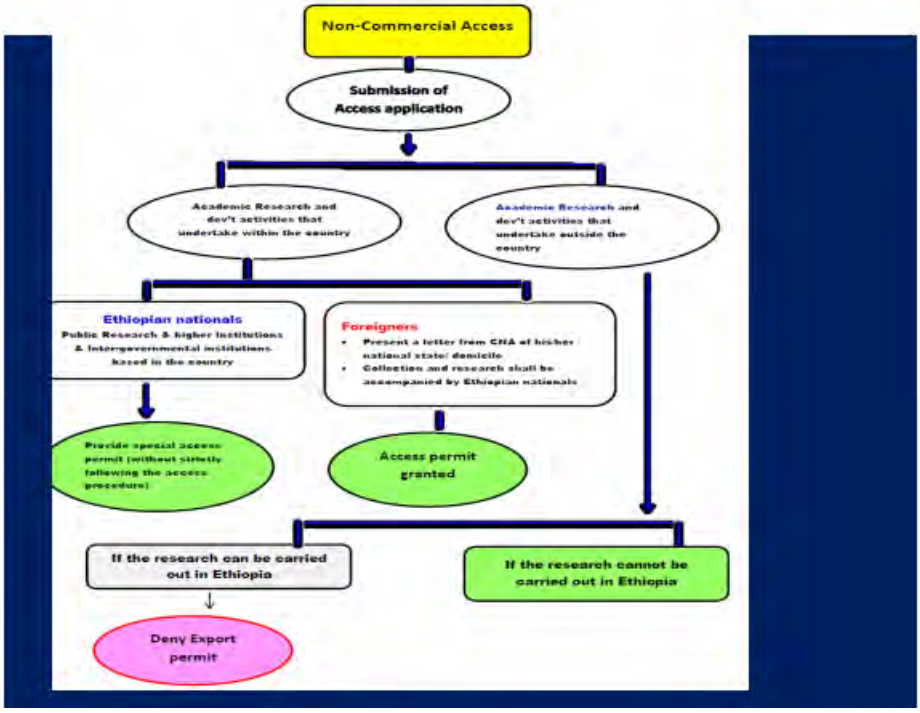

Fig. 7: Flow Chart Ethiopia 4

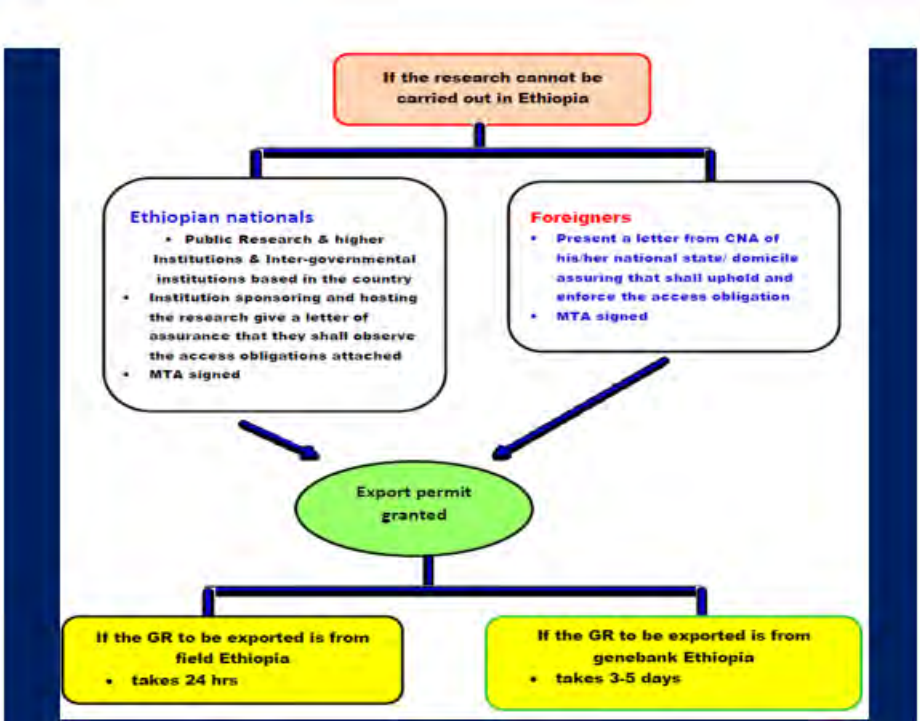

Fig. 8: Flow Chart Ethiopia 5

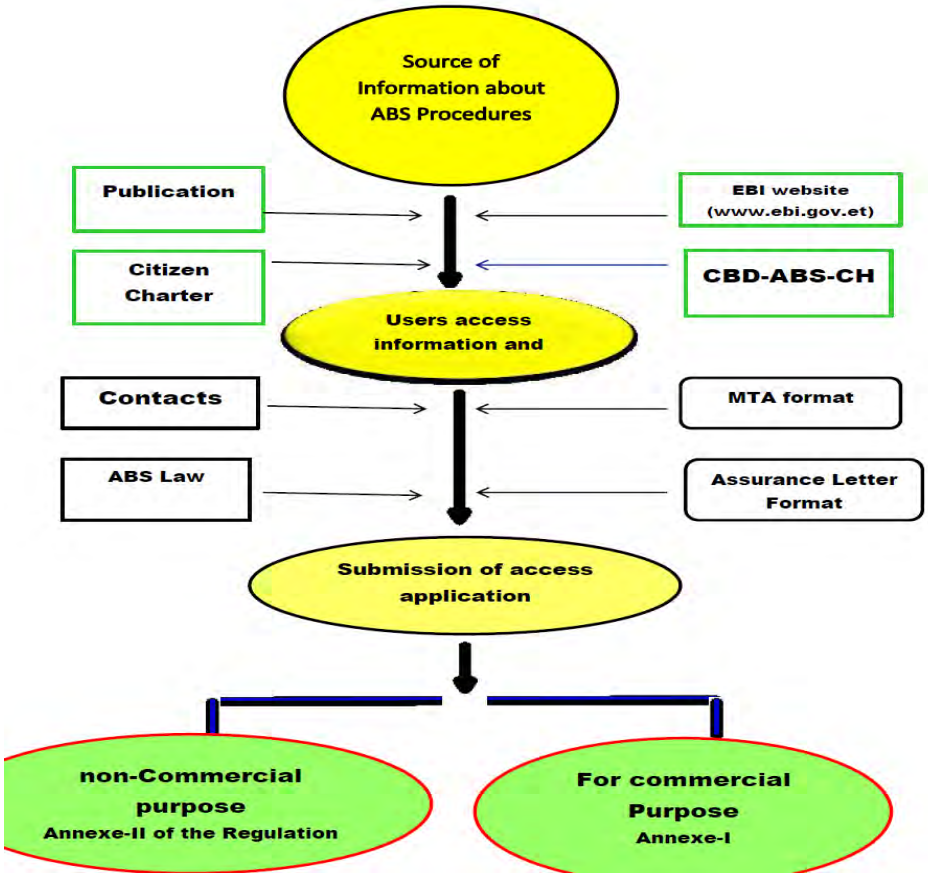

Fig. 9: Flow Chart Ethiopia 6

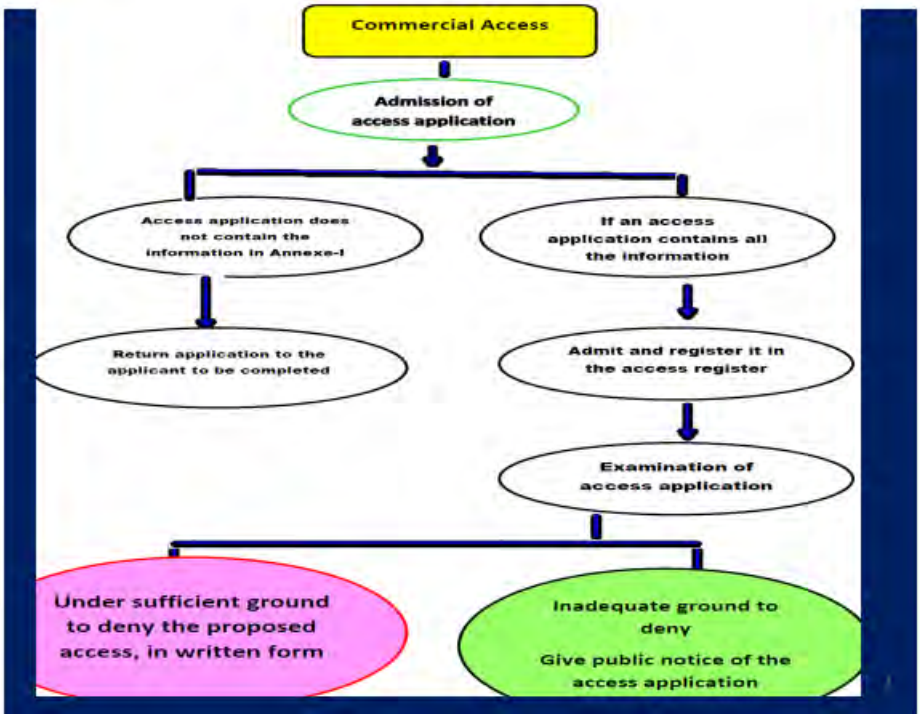

Fig. 10: Flow Chart Ethiopia 7

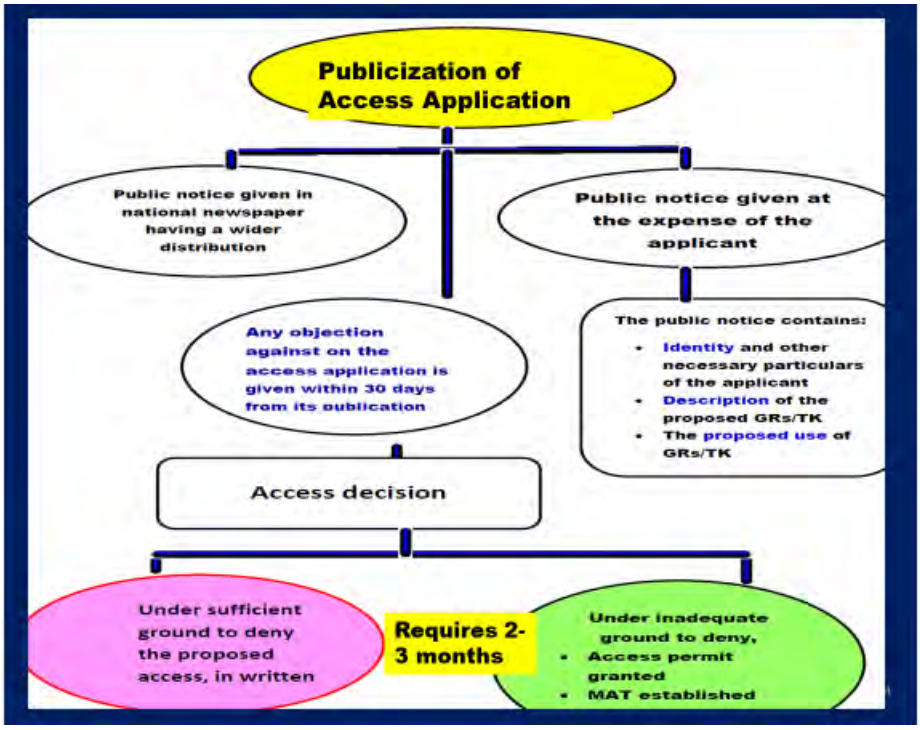

Fig. 11: Flow Chart Ethiopia 8

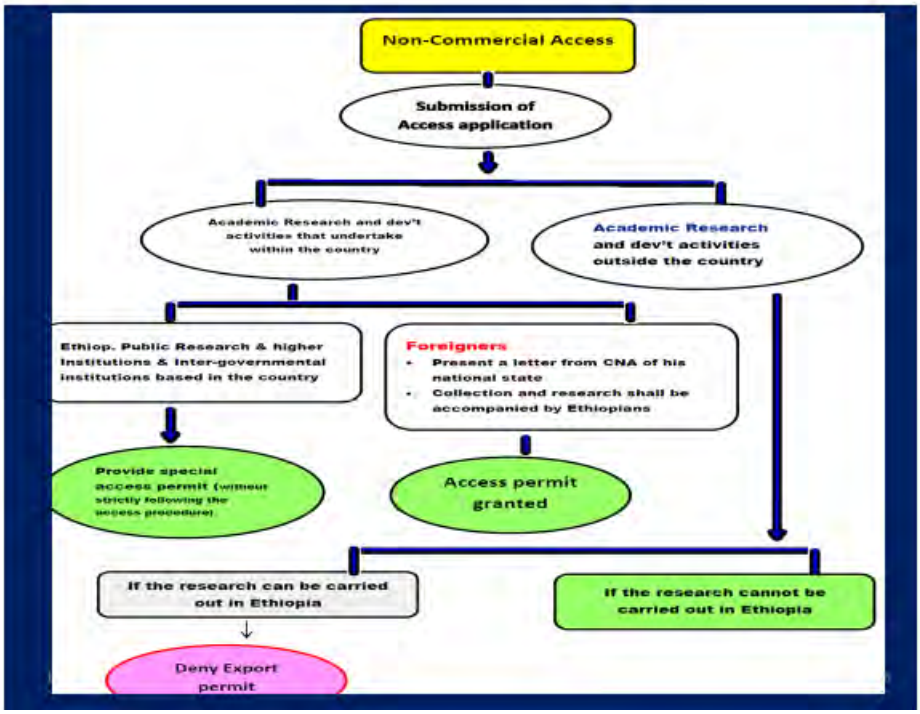

Fig. 12: Flow Chart Ethiopia 9

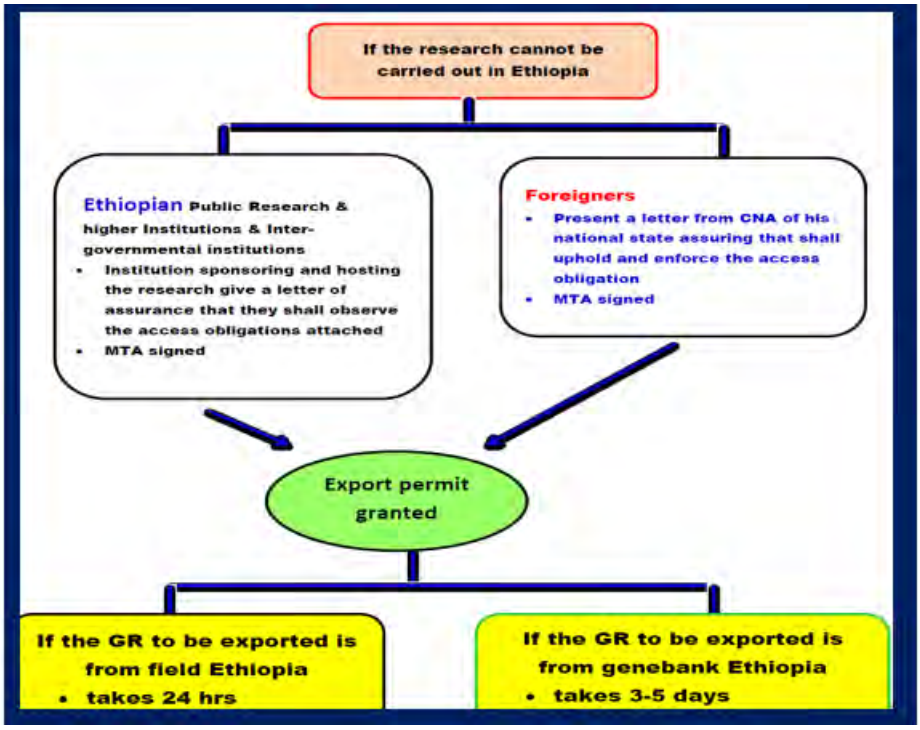

Fig. 13: Flow Chart Ethiopia 10

6.2 Questions and Answers

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

- An issue that sparked debate among participants concerns a basic pre-condition of access in Ethiopia: According to the Ethiopian ABS law (see Article 12.4 of Proclamation No. 482 / 2006) a foreign applicant shall present a supportive letter from the competent authority of his / her national state assuring that they will uphold and enforce the access obligations of the applicant. Participants argued that it is not possible for Competent National Authorities in Europe or elsewhere to assume this role for several reasons (principle of sovereignty, human resources, etc.). Participants further enquired whether it is easy for Ethiopia to obtain such letters. What about countries such as the U.S. that do not have CNAs? According to the Ethiopian ABS National Focal Point, the supportive letter does not need to be issued by a CNA but may be issued by any responsible entity in the relevant Ministry of the applicant state.
- Closely linked with this question of presenting a letter from the CNA, the following question was posed: If a foreign institution wants to undertake research with a partner in Ethiopia, does a partnership with a local counterpart suffice or is the user required to present two letters (one from the institution and one from the CNA) to the Ethiopian authorities? According to the Ethiopian ABS system, the user is required to present two letters.
- How long does it take to obtain an export permit? A permit can be completed within 24 hours (in situ) or 3-5 days (ex situ).
- An Ethiopian ABS case (ABS agreement on *Osyris* spec.. signed between the Ethiopian Biodiversity Institute and Docomo Oils PLC.) was presented. The US based company Docomo Oils PLC is establishing an industry in Ethiopia for processing herbal compounds, extraction of essential oils and the manufacturing of other related herbal and cosmetics products. The user may harvest, collect and process essential oils of the shrub from the area stated in the agreement. Participants enquired why the duration of the agreement is limited to 10 years and what this means in terms of the future of the industry? In response it was argued that there should be an environmental assessment / evaluation after 10 years. A contract may be renewed if the company uses the resource sustainably. Since this is not certain, it is fixed as a condition to ensure sustainability.

6.3 Access Profile

Tab. 2: Access profile Ethiopia

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	Yes		ABS -CH
Signatory	No		ABS -CH
NFP (National Focal Point)	Yes		ABS -CH
Contact NFP	+251 916 458972; +251 941 295966; ashenafiaye-new@ibc.gov.et		ABS -CH
CNA (Competent National Authority)	Yes		ABS -CH
Contact CNA	+251 916 458972; ashenafiaye-new@ibc.gov.et		ABS -CH
CNA Deputy	No		
Contact CNA Deputy	Telephone Email		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	No	No. However, established rules and procedures for MAT are stipulated in Proclamation No. 482/2006 Article 16.1-13 - "Contents of Access Agreement"	
ABS law	yes	Access to Genetic Resources and Community Knowledge and Community Rights Proclamation (Proclamation No. 482/2006). This Proclamation, which has the force of Law, concerns the protection and enhancement of customary use of genetic resources by Ethiopian communities which are relevant to the conservation and sustainable use of the biodiversity resources of the country. It provides rules relative to the access to genetic resources and community knowledge on use of those genetic resources, and provides for the rights of communities over genetic resources and community knowledge in conformity with the Convention.	ABS-CH, Faolex
Specific access regulation	Yes	Council of Ministers Regulation to provide for Access to Genetic Resources and Community knowledge, and Community Rights (No. 169/2009)	ABS-CH, Faolex

Criteria	Acquired information	Comments	Source
		This Regulation, made under the Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation, provides rules relative to the application under section 14 of the proclamation to access genetic resources and/or community knowledge. An application shall be examined and made public. The Regulation also concerns procedures for non-commercial access and a multilateral system of access.	
Specific access procedures (law or any defined process) for non-commercial use	Yes	Council of Ministers Regulation to provide for Access to Genetic Resources and Community knowledge, and Community Rights (No. 169/2009) This Regulation, made under the Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation, provides rules relative to the application under section 14 of the proclamation to access genetic resources and/or community knowledge. An application shall be examined and made public. The Regulation also concerns procedures for non-commercial access and a multilateral system of access.	ABS-CH, Faolex
English translation for users	Yes	Amharic, English	ABS-CH
Visualization of ABS procedure	no information		
Information on access procedure / regulations accessible through weblink	Yes	https://absch.cbd.int/database/record/ABSCH-MSR-ET-208211	ABS-CH
Access demand form	Yes	See Annex I ("Form of Commercial Access Application") of Regulations No. 169/2009	Regulations No. 169/2009
Specific access demand form for non-commercial purposes	Yes	See Annex II ("Form of Non-Commercial Access Application") of Regulations No. 169/2009	Regulations No. 169/2009
Online application system	No		
Compulsory documents for access demand application	Yes	Yes, there is MTA form and assurance letter sample these are found in the Ethiopian Biodiversity Institute website: www.ebi.gov.et	EBI website:www.ebi.gov.et

Criteria	Acquired information	Comments	Source
Submission of access application at	Ethiopian Biodiversity Institute (former: Institute of Biodiversity Conservation)		Regulations No. 169/2009
Access fees	Yes	Only for access under the multilateral system access and the amount vary (it depends up on the cost for maintaining and provising GRs.	Regulations No. 169/2009
Other permits prerequisite to obtain ABS permit	No		
IRCC (Internationally Recognised Certificate of Compliance)	No		
Have ABS permit(s) been issued in the country?	Yes	Three MAT on Withania somnifera, Osyris species and Dichrostachys cinera was signed between Ethiopian Biodiversity Institute and DOCOMO Oils plc. a private USA based company on 6 July 2012 for the purpose of producing essential oils, cosmetics and herbal medicine.	
ABS permit(s) issued by	Ethiopian Biodiversity Institute (EBI)		
Average timeline (from access demand to permit)	timeline defined	For commercial purpose at least 1 month and for non-commercial purpose 48 hr.	
MAT(s) signed	Yes		
MAT(s) to be signed with	Ethiopian BiodiversityInstitute (former: Institute of Biodiversity Conservation)		
Standard MAT clauses	No	No. However, established rules and procedures for MAT are stipulated in Proclamation No. 482/2006 Article 16.1-13 - "Contents of Access Agreement"	
PIC(s) granted	Yes		
PIC(s) to be granted by	1) Ethiopian BiodiversityInstitute (for access to GR) 2) Local community (for access to community knowledge)		Regulations No. 169/2009

7 Access Procedures of India

Dr. Atul Kumar Gupta, Principal Chief Conservator of the Forests and Member of the Secretary, Tripura Biodiversity Board;

Mr. Thangapandian Rabikumar, Secretary, National Biodiversity Authority

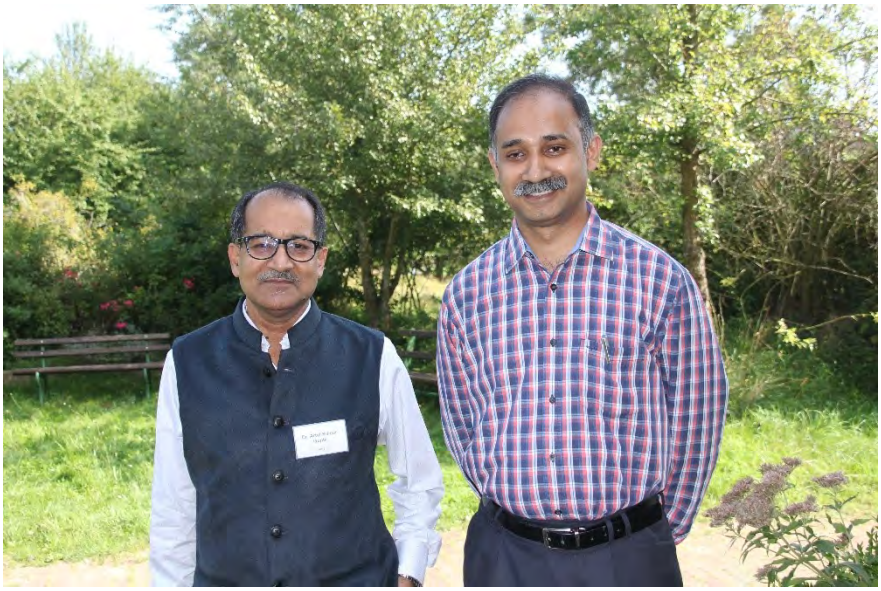

Fig. 14: Dr. Atul Kumar Gupta and Mr. Thangapandian Rabikumar

7.1 Country Presentation

Introduction

India is one of the recognized mega diverse countries occupying 2.4% of the global geographical area and harboring 7 to 8 % of globally recorded species. Four of the 34 identified hotspots in the world are found in India. India is also rich in traditional knowledge associated with the biological resources. This traditional knowledge occurs in ancient texts as well as in oral undocumented traditions.

India is a party to the Convention on Biological Diversity (CBD) and also to Nagoya Protocol on Access and Benefit Sharing. Ministry of Environment, Forest and Climate Change (MoEFCC) is the nodal ministry which acts as the focal point for CBD and Nagoya Protocol. MoEFCC is also publishing authority for Access and Benefit Sharing Clearing House (ABSCH). The National Biodiversity Authority (NBA) is designated as the competent National Authority for Nagoya Protocol on ABS which is also the national authorized user for ABSCH.

Biological Diversity Act, 2002

Government of India enacted the Biological Diversity Act (BD Act) in 2002 and notified the Biological Diversity Rules in 2004 to give effect to the provisions of the CBD. The objectives of the BD Act are:

1. Conservation of Biological Diversity
2. Sustainable use of its components and
3. Fair and equitable sharing of benefits arising out of the biological resources and knowledge associated thereto.

India also notified the Guidelines on access to biological diversity resources and associated knowledge and benefit sharing regulations in 2014 (ABS Regulations, 2014).

The BD Act is aimed at protecting the sovereign rights of India over its biological resources and to prevent the misuse and misappropriation of biological resources occurring in or obtained from India. The BD Act also protects biological diversity and associated traditional knowledge by documenting them in the form of Peoples' Biodiversity Register (PBR). The BD Act regulates the access and use of biological resources and/ or associated knowledge for certain activities. The BD Act also ensures sustainable utilization of biological resources and equitable benefit sharing from the use of the same. It also provides legal recognition and supports the biodiversity and associated TK in the country.

Institutional mechanism under BD Act

The BD Act is implemented through a three-tier institutional mechanism, at national level, NBA was established in October 2003 in Chennai under section 8 of the BD Act; At the provincial level, State Biodiversity Boards (SBB) are established by the representative provincial governments; and at the Community /local body level, Biodiversity Management Committees (BMC) are established for the purpose of promoting conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals, microorganisms and chronicling of knowledge relating to biological diversity.

Composition of National Biodiversity Authority

The composition of NBA includes a Chairperson, 10 ex-officio members representing various ministries of the union government and five nominated expert members. The functions of NBA include issuing of guidelines on ABS, grant approval for access, advice the central and state government on biodiversity related matters and to oppose grant of Intellectual Property Rights (IPR) outside India on any biological resources obtained from India illegally.

Activities regulated under BD Act

The scope of the BD Act includes regulates the activity relating to access to biological resources and/ or associated knowledge. When any person desires to access the biological resources and/or associated knowledge for the purpose of research, bio-survey, bio- utilization, commercial utilization, obtaining IPR based on biological resources obtained from India, transfer the results of research and transfer already accessed biological resources and associated knowledge to third party, needs prior approval under the provisions of the BD Act. The details are as below:

Tab. 3: Application forms for different activities

Form	Category and timeline	Who should apply?
Form I	Access to Biological resources occurring in India and associated traditional Knowledge *(Application may be disposed within a period of 6 months as per the BD Rules)*	Non-Indian[2], NRI, Non-Indian entity or Indian entity having non-Indian participation in its share capital or management
Form II	Transferring the results of research *(Application may be disposed within a period of 3 months as per the BD Rules)*	Any Indian / non-Indian or Indian[3] / non-Indian entity to any non-Indian, NRI, non-Indian entity or Indian entity having non-Indian participation in share capital or management
Form III	Applying for Intellectual Property Rights for inventions based on any research or information on a biological resource obtained from India *(Application may be disposed within a period of 3 months as per the BD Rules)*	Any Indian/ non Indian or entity
Form IV	Third Party transfer of the accessed biological resources and associated traditional knowledge. (*Application may be disposed within a period of 6 months as per the BD Rules)*	Any person who obtained approval of NBA in Form I, to Indians / non-Indians or entities
Form-B	Conducting of non-commercial research or research for emergency purposes outside India by Indian researcher's / Government institutions *(Application may be disposed within a period of 45 days as per ABS Regulations, 2014)*	Indian Researchers/ Government Institutions

NBA has introduced an online portal viz e-filing of ABS application to file the application with NBA seeking approval for accessing biological resources and/or associated knowledge under BD Act. This is aimed at providing a user-friendly platform for the potential users of biological resources from India. The online portal may be accessed through this link: http://absefiling.nic.in

Processing of ABS Application

The access applications received at NBA, after a preliminary scrutiny of the application, the same would be referred to SBBs for obtaining consent or otherwise of the BMC or the local bodies concerned. Thereafter, the application is placed before a committee of experts along with inputs of the local bodies for examination and recommendation of the EC is placed before the Authority (Governing Body) for consideration. On the approval of the Authority, a draft agreement containing mutually agreed terms (MAT) is sent to the user for execution/ signature. Every approval given under BD Act is in the form of an agreement signed between the user and a representative of NBA. After signing the agreement, it is uploaded in the

2 Natural/ legal who falls under section 3(2) of the BD Act will be treated as Non-Indian i.e (a) a person who is not a citizen of India; (b) a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 196 1; (c) a body corporate, association or organization- (i) not incorporated or registered in India; or (ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management.

3 Natural/ legal who falls under section 7 of the BD Act will be treated as Indian

ABSCH to generate IRCC.

ABS Regulations, 2014

The ABS regulations 2014 provides legal certainty, clarity and transparency. The objective of the regulations is to provide guidance to the users on procedure to access to biological resources and/ or associated knowledge for various activities. It also provides a simplified procedure to Indian researchers and government institute for conducting of non-commercial research or research for emergency purposes outside India by Indian researcher's / Government institutions. It provides different options for benefit sharing with a graded percentage terms. It also provides the apportioning of the accrued benefits to the community/BMC.

The BD Act exempts prior approval for local people and communities to access bio resources for the use in India. The growers and cultivators, vaids and hakims (Practitioners of traditional medicine system) are also exempt under the BD Act to use biological resources for bona-fide purposes. Collaborative research projects involving transfer or exchange of biological resources or information relating thereto through the government sponsored institutions which are in conformity with the guidelines (2006) issued by the Ministry of Environment, Forest and Climate Change are also exempted.

India is also party to the ITPGRFA, it is obliged to provide exemption in order to respect those treaties. Thus, MOEFCC issued notification under section 40 of the BD Act for exempting such crops listed under Annex-I of the ITPGRFA, as notified by the Ministry of Agriculture, Government of India from the purview of the sections 3 and 4 of the BD Act.

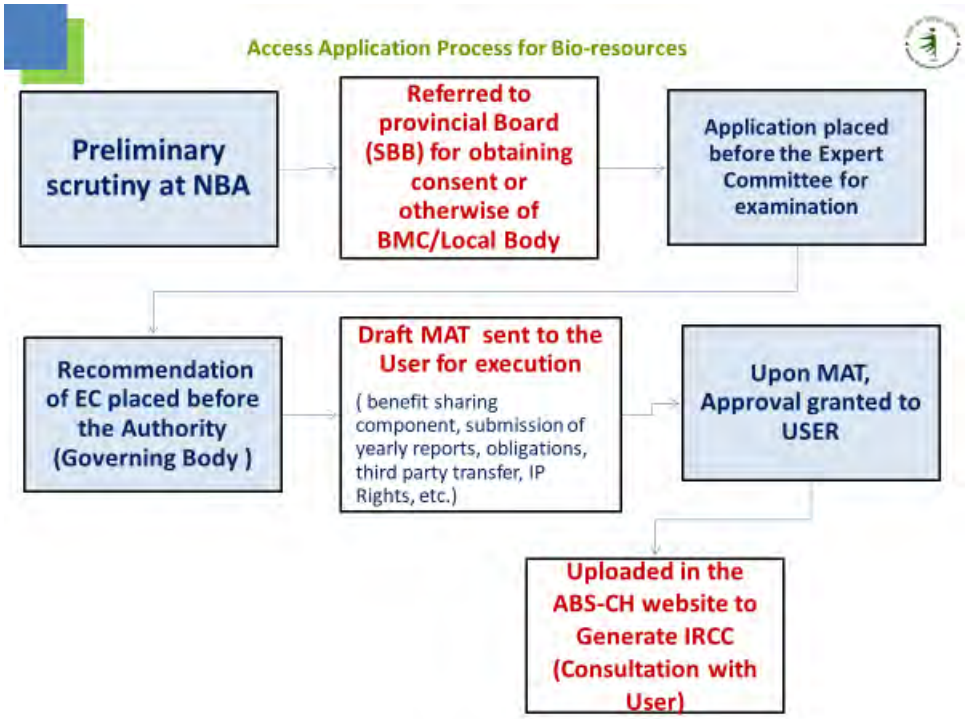

Fig. 15: Flow Chart India

7.2 Questions and Answers

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

- In India you use the term biological resources. What is covered under this definition? Biological resources means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but it does not include human genetic material.
- The Biological Diversity Act was enacted in 2002 on the lines of the CBD. To implement the provisions of the Biological Diversity Act, the National Biodiversity Authority (NBA) was established in October 2003. A question raised by participants related to the institutional structure for implementing the Biological Diversity Act. Why does India use the service of the so-called State Biodiversity Boards? India is a diverse country where many different languages are used. State biodiversity boards are established by the State Governments and have three main functions: (1) They advise the State Government, subject to guidelines issued by the Central Government, on conservation of biodiversity, sustainable use of its components and equitable sharing of benefits; (2) They regulate by granting of approvals or otherwise requests for commercial utilization or bio survey and bio utilization of any biological resource by Indians; (3) They perform other functions as necessary to carry out the provisions of the Act or as prescribed by the State Government.
- Should users approach local communities directly under the Indian ABS system? No, India uses a “single window” approach for users. The user only needs to address the National Biodiversity Authority (NBA) which is responsible for granting approval for access. The NBA engages with the community.
- How does India address the situation where traditional knowledge is owned by more than one local community? Would a mapping of places with TK be worth considering? In India, all agreements are signed by the national state authority. Authorities are often not informed how many communities hold this knowledge. Benefits are channeled to the national state authority and then sent back to the community. A mapping of all places with TK in India is not feasible due to the sheer size of communities holding traditional knowledge throughout the country.
- If a non-Indian user is doing research with a biological resource from India, is a distinction made between commercial and non-commercial research? Research for both commercial and non-commercial purposes requires prior approval by the relevant authority.
- India takes samples of genetic resources that are being used for research and development. If the volume of ABS agreements increases, taking samples may become a burden. For now, this approach is possible because there are only around 1200 access agreements.
- In India, recorded TK exists in ancient texts. This information has been translated into English and recorded in the Traditional Knowledge Digital Library (TKDL). Patent offices have access to this network. A team scrutinizes all patent applications as soon as they are published through a database. They may file an objection report if prior art exists in a particular case.
- Does India have a timeline for access to genetic resources? The timeline is 6 months.

In many cases it is not possible to get approval within 6 months for several reasons: receiving information from the applicant takes times. Further, expert committees from all parts of the country need to meet which only occurs once every two months.

7.3 Access Profile

Tab. 4: Access profile India

Criteria	Acquired information	Comments	Sourcee
Party Nagoya Protocol	yes		ABS -CH
Signatory	yes		ABS -CH
NFP (National Focal Point)	yes		ABS -CH
Contact NFP	Ms. Sujata Arora +91 11 24695135; sujata@nic.in		ABS -CH
CNA (Competent National Authority)	yes	National Biodiversity Authority	ABS -CH
Contact CNA	+91 44 2254 2777; secretary@nbaindia.org; chairman@nba.nic.in; secretary@nba.nic.in	www.nbaindia.nic.in	ABS -CH
CNA Deputy	Not applicable		
Contact CNA Deputy	Not applicable		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	Not applicable		

Criteria	Acquired information	Comments	Sourcee
ABS law	yes	The Biological Diversity Act 2002: An Act to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto. https://absch.cbd.int/database/record/ABSCH-MSR-IN-202011 The Biological Diversity Rules 2004: Biological Diversity Rules, 2004 lays down various forms, fees, time lines and procedures to facilitate the applicants in obtaining prior approval of the National Biodiversity Authority (NBA) for various activities under the Biological Diversity Act. https://absch.cbd.int/database/record/ABSCH-MSR-IN-201984	ABS-CH
Specific access regulation	yes	Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 https://absch.cbd.int/database/record/ABSCH-MSR-IN-202163	ABS-CH
Specific access procedures (law or any defined process) for non-commercial use	yes	According to ABS Regulations 2014 this is applicable only to Government Institution. The Guidelines on Access to Biological Resources and Associated Traditional Knowledge and Benefit Sharing Regulation 2014 provides a specific provision (Form B) which can be used by Indian researchers / Govt institutions, who intend to carry or send biological resources outside India for non-commercial research.	Guidelines 2014
English translation for users	yes	English	ABS-CH
Visualization of ABS procedure	yes	A schematic presentation of processing applications under Biological Diversity Act, 2002 and Rules 2004 exists http://nbaindia.org/content/684/62/1/applicationprocess.html	NBA website
Information on access procedure / regulations accessible through weblink	yes	Application forms for access to biological resources and / or associated knowledge, guidelines for filling them and form of agreements are available on the NBA website: www.nbaindia.org	ABS-CH, NBA website

Criteria	Acquired information	Comments	Sourcee
Access demand form	yes	Form I concerns access of biological resources occurring in or obtained from India and / or associated traditional knowledge for research, commercial utilization, biosurvey or bio-utilization. http://nbaindia.org/content/26/59/1/forms.html Guidelines for filling the forms exist: http://nbaindia.org/uploaded/pdf/guidelines/Guidelines_for_filling-up_of_Form-I.pdf	NBA website
Specific access demand form for non-commercial purposes	yes	Regulation 13 of the "Guidelines on Access to Biological resources and associated TK and Benefit Sharing Regulation, 2014" through Form B facilitates transfer of biological resources by government institutions in India to carry out urgent studies to avert emergencies like epidemics, etc.	Guidelines 2014
Online application system	yes	http://absefiling.nic.in/NBA/login/auth Live help is available during office hours (10.00 AM to 5:00 PM), on all working days. A staff member will answer your questions live and guide you further for filling up of application forms. Call : +91 44 2254 2777 or mail to techbs@nba.nic.in. ABS E -filing User Manual: http://absefiling.nic.in/NBA/login/showDc?filename=manual&dataName=manual&id=50	NBA website
Compulsory documents for access demand application	yes	A) Address proof B) Identity proof C) 1. Letter of authorization, if there are more than one applicant or the applicant authorises someone or attorney to represent on his/her behalf; 2. Proof for doing business (for entity) - Document of incorporation; 3. Agreement /MoU / letter of intent with the national R&D institution for collaboration; 4. Agreement / any negotiated instrument between applicant and provider of biological resources http://absefiling.nic.in/NBA/register/faq?csrfPreventionSalt=Wmq07UePgNPlccuhoOcX&aboutNBAId=53	NBA website,
Submission of access application at	National Biodiversity Authority (NBA)		Guidelines 2014
Access fees	yes	10,000 INR	The Biological Diversity Rules 2004 (see Art. 14)
Other permits prerequisite to obtain ABS permit	Not applicable		

Criteria	Acquired information	Comments	Sourcee
IRCC (Internationally Recognised Certificate of Compliance)	yes	74 IRCCs are listed on the ABS-CH (commercial and non-commercial)	ABS-CH
Have ABS permit(s) been issued in the country?	yes	The permits (approval) details are available in the website of NBA http://nbaindia.nic.in	NBA website
ABS permit(s) issued by	National Biodiversity Authority (NBA)	The National Biodiversity Authority may give approval after consulting BMC (local body) through State Biodiversity Board. The approval shall be in the form of an Agreement establishing mutually agreed terms and an equitable benefit sharing between the users of the biological resources and associated knowledge and concerned local bodies and benefit claimers.	ABS-CH
Average timeline (from access demand to permit)	timeline defined	The Authority shall after consultation with the concerned local bodies and collecting such additional information from the applicant and other sources, as it may deem necessary, dispose of the application, as far as possible, within a period of six months from the date of its receipts.	ABS-CH; Faolex (see Art. 14 (3) Biological Diversity Rules 2004)
MAT(s) signed	yes	The MAT signed details are available in the website of NBA http://nbaindia.nic.in	NBA website
MAT(s) to be signed with	National Biodiversity Authority (NBA)		Guidelines 2014
Standard MAT clauses	yes	Model caluses of MAT to be executed between National Biodiversity Authoiryt and the user has been developed on the basis of Rule 14 (6) .	
PIC(s) granted	yes	The MAT inclusive of PIC and the granted details are available in the website of NBA http://nbaindia.org/content/683/61/1/approvals.html	NBA website
PIC(s) to be granted by	National Biodiversity Authority (NBA)		Guidelines 2014

8 Access Procedures of Brazil

Mr. Marcelo Böhlke, Head of the Environment Division (DEMA), Ministry of Foreign Affairs of Brazil, ABS National Focal Point;

Mr. Rafael Marques, Brazilian Ministry of Environment and Management Council of Genetic Heritage (CGen)

Fig. 17: Mr. Marcelo Böhlke

Fig. 16: Mr. Rafael Marques

8.1 Country Presentation

General information on ABS

Status of ratification of CBD and Nagoya Protocol

Brazil ratified the Convention on Biological Diversity in 1994 and implemented it in its national legal order by means of Decree 2519 of 16 March 1998. Brazil signed the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity in 2011 and has not ratified it yet. The Nagoya Protocol is still under consideration by the National Congress. It is expected to be approved by the National Congress soon, so that the Government will be able to ratify it.

Legal framework for ABS implementation

The two main pieces of legislation regarding ABS implementation are Law n. 13,123/2015 and Decree n. 8,772/2016. This new legislation comes to replace the former Provisional Measure 2186-16 of 23 August 2001.

Law n. 13,123 of 20 May 2015 sets out the general framework for access to genetic resource, for protection and access to associated traditional knowledge and for benefit-sharing for the conservation and sustainable use of biodiversity.

Decree n. 8,772 of 11 May 2016 complements the provisions contained in Law n. 13,123 by providing details on the Genetic Resource Management Council (CGen, the Brazilian National Competent Authority), associated traditional knowledge, the electronic National Management System of Genetic Resource and Associated Traditional Knowledge (SisGen), benefit-sharing, administrative offenses and penalties, National Fund for Benefit-Sharing (FNRB), among other issues.

The main objectives of the new legislation are to ensure: legal certainty, low transaction costs, benefits channeled to conservation, fair and equitable sharing of benefits and promoting access to genetic resources and associate traditional knowledge and foster innovation.

A key concept in the Brazilian legislation is that benefit-sharing is the only way to facilitate access.

Benefit-sharing is the guarantee of access/utilization facilitation. This represents an intermediate position between genetic resources user views (who tend to prioritize rules facilitating access/utilization with less concern with benefit-sharing obligations) and genetic resources provider approach that may require too strict rules for access authorization making genetic resource research and development difficult to make.

This approach is essential to create trust among the parties which may be key to a functional international ABS system. Brazil has developed this understanding after 15 years of internal debate based on the peculiar position of being at the same time a strong user of exotic genetic resources and a megadiverse provider of genetic resources and associated traditional knowledge.

Institutional framework for ABS implementation

The institutional framework for ABS in Brazil is comprised of: Genetic Resource Management Council (CGen): CNA; Benefit-Sharing National Fund (FNRB): insurance for users and traditional knowledge holders; Benefit-Sharing National Programme (PNRB): guidelines for the use of FNRB funds; Electronic System of GR and TK (SisGen): single window. Compliance authorities (IBAMA, in some cases with the Ministry of Agriculture, Livestock and Supply or the Navy Command); Checkpoints: SisGen, ANVISA, Patent Office (INPI), Cultivar National Authority (RNC); Traceability system: CNPq, CTNBio, SISCOMEX, INPI, ANVISA, RFB, SNIIC and other databases.

CGen is a normative, advisory and appellate Council, responsible for coordinating the development and implementation of policies for managing all the access to genetic resource and associated traditional knowledge and benefit-sharing, composed by representatives from different entities and bodies of the federal public administration with jurisdiction over the different actions, in a maximum of 60% (sixty percent), and by representatives from members of society, in no less than 40% (forty percent), ensuring parity of: business sector; academic sector; and indigenous peoples, traditional communities and traditional farmers.

Law 13,123/2015 provides that research and development is to be carried out freely. There is no PIC requirement for access/utilization of genetic resources without associated traditional knowledge. A registration is required only at the time of publication of the results, or upon application for a patent, or before introduction of a product on the market.

Access to associated traditional knowledge is dependent on obtaining prior informed consent. Proof of prior informed consent can occur at the discretion of the indigenous population, traditional community or traditional farmer, by means of the following documents according to regulations: signed prior consent; registered audiovisual consent; statement from the official governing body; or adherence to the provisions set forth by community protocol.

The Brazilian National Focal Point is the Ministry of Foreign Affairs.

How to access genetic resources or associated traditional knowledge in Brazil

Law 13,123/2015 provides that research and development is to be carried out freely. PIC has been granted and MAT has been defined by means of legislation by the National Congress for access or utilization of genetic resources without associated traditional knowledge. Access to associated traditional knowledge is dependent on obtaining prior informed consent from the owner or the provider of the traditional knowledge (intellectual property right). Proof

of prior informed consent can occur at the discretion of the indigenous population, traditional community or traditional farmer.

Access to genetic resource or associated traditional knowledge can be carried out within the country by: national legal or natural person, public or private; or a legal person based abroad associated to a national scientific and technological research institution, public or private.

Shipment of genetic resource sample to a foreign country with the purpose of access must be previously registered at SisGen.

Sending a sample containing genetic resource to a foreign country by a national legal person, public or private, for services as part of research or technological development must be registered along with access registration at SisGen.

No difference between access for commercial and non-commercial purposes

According to the Brazilian legislation, access to genetic resource means research or technological development carried out on genetic resource samples. There is no difference between access for commercial and non-commercial purposes.

The benefits resulting from economic exploitation of finished goods or reproductive material arising from access to genetic resource of species found in *in situ* conditions or to associated traditional knowledge, even if produced outside the country, will be shared in a fair and equitable way.

In the case of a finished product, the genetic resource or the associated traditional knowledge component must be one of the key elements of value adding to the product.

Only the manufacturer of the finished product or the producer of the reproductive material will be obliged to share benefits, regardless of who has previously carried out access activities.

The manufacturers of intermediate products and developers of processes originating from the access to genetic resource or associated traditional knowledge along the production chain will be exempted from benefit-sharing obligations.

Procedures and timelines for access to genetic resources or associated traditional knowledge

There is no timeline for access to genetic resources.

There is a need for prior informed consent and mutually agreed terms with regards to traditional knowledge associated with genetic resources. It is a private contract between the provider and the user of traditional knowledge. There is no direct interference from the state.

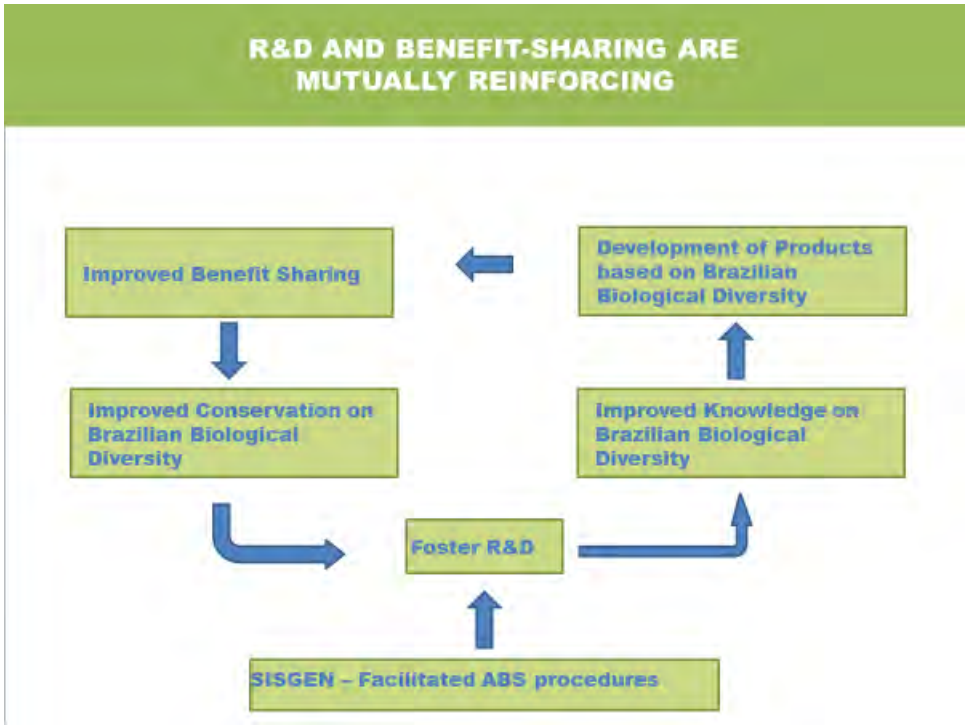

Fig. 18: Flow Chart Brazil

8.2 Questions and Answers

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

- Legislation on ABS in Brazil was adopted in 2000. New domestic legislation on ABS was adopted in 2015: Law 13, 123 / 2015 and Decree 8, 772/2016. The main objectives of the new ABS legislation are: legal certainty, low transaction costs, benefits channeled to conservation, assuring fair and equitable sharing of benefits, promoting access to GR and TK and foster innovation. A question that arose was whether applications have ever been rejected under the earlier system of Brazil. This has been the case when the Genetic Resource Management Council CGEN (CNA) found that benefit-sharing was not fair and equitable. Most often users renegotiated with resource providers and applications were approved.
- Brazil's new approach is based on the following premise: Assured benefit-sharing in the future is the guarantee of access / utilization facilitation at present. This approach is essential to foster trust among the parties which is key to a functional ABS system.
- Why is there no need to obtain prior informed consent (PIC) and enter into mutually agreed terms (MAT) for genetic resources under Brazil's new approach? Brazil aims to facilitate research and development. It uses an administrative verification process after registration, a traceability system and other measures to guarantee benefit-sharing.
- To access genetic resources in Brazil, neither a PIC nor a negotiated MAT is required. Instead Brazil uses a registration system. Does Brazil give registrations a reference number or are they just for internal use? At the end of the process, the user receives a certificate which is being sent to the ABS Clearing-House. Registration in Brazil is considered as an Internationally Recognized Certificate of Compliance (IRCC).

- Is benefit-sharing in Brazil fixed or is there a margin for negotiation? Concerning genetic resources, there is a fixed percentage for monetary benefit-sharing (1% of annual net revenue). Concerning traditional knowledge, the user must negotiate with the TK provider and pay 0.5% to the benefit-sharing national fund (FNRB). The FNRB provides legal certainty and insurance for users and TK holders.
- In Brazil, the use of genetic resources includes the use of digital sequence information.

8.3 Access Profile

Tab. 5: Access profile Brazil

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	no		ABS -CH
Signatory	yes		ABS -CH
NFP (National Focal Point)	yes	Mr. Marcelo Böhlke, Head of Environment Division at the Ministry of Foreign Affairs of Brazil	MFA
Contact NFP	0055 61 2030 8450, 8447 dema@itamaraty.gov.br marcelo.bohlke@itamaraty.gov.br		ABS -CH
CNA (Competent National Authority)	yes	CGEN (Genetic Heritage Management Council) Brazil has established a unique, integrative agency, CGEN (Genetic Heritage Management Council) to grant authorisation for access to genetic resources and ATK. It is constituted by representatives from 9 ministries and 10 federal organisations including federal research institutions and organisations that represent traditional communities.	CGEN
Contact CNA	0055 61 2028.2182 cegen@mma.gov.br		ABS -CH
CNA Deputy	yes		
Contact CNA Deputy	yes	National Indigenous Foundation (FUNAI); National Council of Peoples and Traditional Communities (CNPCT); Fundação Cultural Palmares (FCP); National Council for Sustainable Rural Development (CONDRAF).	Ministry of Environment
Relevant competent authorities of IPLCs (Indigenous Peoples and Local	yes	Law 13,123 (2015), ABS law which replaces the former Provisional Measure.	individual research

Criteria	Acquired information	Comments	Source
Communities)			
ABS law	yes	Decree 8,772 (2016). Furthermore there are complementary regulations to Law 13,123, which detail application procedures, model forms etc.	individual research
Specific access regulation	yes	The Brazilian system establishes an online electronic system for registration for both scientific research (non-commercial research), and for technological development (commercial research). Currently, there are different registration forms for non-commercial and for commercial research but they follow the same procedure. There is no administrative procedure for obtaining PIC for access to genetic resources exclusively. PIC for access to TK should be obtained with the holder of the TK. When technological development reaches the stage for commercialization, a product notification procedure is the trigger for MAT requirement.	Ministry of Environment
Specific access procedures (law or any defined process) for non-commercial use	no		
English translation for users	Unofficial translation	National Indigenous Foundation (FUNAI); National Council of Peoples and Traditional Communities (CNPCT); Fundação Cultural Palmares (FCP); National Council for Sustainable Rural Development (CONDRAF).	Ministry of Environment
Visualization of ABS procedure	yes	Basically, through the online review of the law and regulation and FAQ sections. http://www.mma.gov.br/patrimonio-genetico/acesso-ao-patrimonio-genetico-e-aos-conhecimentos-tradicionais-associados	Law 13,123
Information on access procedure / regulations accessible through weblink	yes	There is information on granted ABS applications.http://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico/processos Applicants may also request online information through cgen@mma.gov.br	CGEN web site
Access demand form	yes	Link not operational at this moment (sisgen.gov.br)	Ministry of Environment
Specific access demand form for non-commercial purposes	yes	Link not operational at this moment (sisgen.gov.br)	Ministry of Environment
Online application system	Not operational yet	National Register for the Management of the Genetic Heritage - (SISGEN)	CGEN web site

Criteria	Acquired information	Comments	Source
Compulsory documents for access demand application	Yes	Project description, researchers involved, type of research (bioprospecting, industrial application, basic research)	Law 13,123 and regulation
Submission of access application at	CGEN	SISGEN (sisgen.gov.br) is not online yet, but it is expected to beavailable in the next few weeks.	Ministry of Environment
Access fees	no information	There are no access fees.	Ministry of Environment
Other permits prerequisite to obtain ABS permit	Yes	There is the need for approvals by ICMBio if ABS actvities are to take place in protected areas; FUNAI if indigenous peoples lands are involved; National Council for Technological Development if foreigners are involved in collecting activities; National Defense Council if access takes place in area indispensable for national security (borders). grants multiple-year authorisations	Ministry of Environment
IRCC (Internationally Recognised Certificate of Compliance)	yes	Law 13,123/2015 provides that IRCC shall be issued by CGEN upon request.	ABS CH, Ministry of Environment
Have ABS permit(s) been issued in the country?	Yes	Number of permits issued by CGEN and its accredited institutions from 2001 to 2015 = 2,156 access authorizations for GR and / or TK.	Ministry of Environment
ABS permit(s) issued by	CGEN	All applications have been published in the Official Gazette - see http://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico/processos	CGEN web site
Average timeline (from access demand to permit)	timeline not available	From 2001 to 2015, average timeline varies widely depending whether the application process is initially fully instructed (from 5 months to a few years). Since November 2015, when Law 13,123/2015 came into force, there is no need for permit before research and development.	Ministry of Environment
MAT(s) signed	yes	Number of MATs signed from 2001 to 2015 = 295 Contracts of Utilization of Genetic Heritage and Benefit Sharing	Ministry of Environment
MAT(s) to be signed with	CGEN (Ministry of the Environment)	From 2001 to 2015 - with the owner of the land where the genetic resource was collected. Since 2015, MATs are to be signed by the Union, represented by the Ministry of Environment of Brazil.	Law 13,123; CGEN
Standard MAT clauses	yes	The Department of Genetic Heritage is currently working on MAT standard clauses under Law 13,123/2015.	Ministry of Environment
PIC(s)	no information	This information is not available, but the number of	Ministry of

Criteria	Acquired information	Comments	Source
granted		PICs granted is approximately the number of permits issued from 2001 to 2015)	Environment
PIC(s) to be granted by	CGEN + indigenous peoples representative organization	From 2001 until 2015, PIC was granted by the land owner where genetic resources was collected or indigenous or local communities in the case of acccess to traditional knowledge. Since 2015 there is no administrative procedure to obtain PIC for access genetic resources exclusively (PIC was granted to all research and development activities through Law No 13,123/2015) . PIC for access to TK are to be granted directly by the indigenous people or traditional communities and communicated to CGen via SISGEN registration procedure.	Law 13,123

9 Access Procedures of Peru

Mr. Marco Enciso (PhD), Director Wildlife Research, Ministry of Agriculture and Irrigation.

Mr. Roger Alberto Becerra Gallardo, Coordinator of the Regulatory Area of Access to Genetic Resources, National Instiute of Agricultural Innovation

Fig. 20: Mr. Roger Alberto Becerra Gallardo

Fig. 19: Mr. Marco Enciso (PhD)

9.1 Country Presentation

REGULATORY FRAMEWORK ON ACCESS TO GENETIC RESOURCES AND DISTRIBUTION OF BENEFITS IN PERU

Overview

Peru is a megadiverse country that is the center of origin of many species of flora and fauna, many of them under the wild, cultivated or domesticated, which are important for global food security, health and comfort, and valuable for their own characteristics and function into the ecosystems.

All of these species represent the genetic potential of the country, and in many cases, are closely associated with the traditional knowledge of the communities and farmers who maintain them and give multiple uses, from food, natural medicines, fuel, industrial (cosmetics, gourmet foods, and others), employing many traditional techniques; and which are also part of their traditional customs as knowledge and all of their Andean and Amazon worldview.

II. Legal Framework

International

- The Convention on Biological Diversity, ratified by Peru through Legislative Resolution Nº 26181 of 1993.
- The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Peru signed on October 8, 2002 and ratified on June 5, 2003 by Supreme Decree Nº 012-2003. Effective since 2004.
- The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. Ratified by Peru on August 7, 2014 and entered into force on December 10, 2014.

Regional

- Decision 391 of the Andean Community of Nations - CAN. establishes a Common Regime

on Access to Genetic Resources. Approved in July 1996.

National

- Law Nº 27811, Law that establishes the regimen of protection of collective knowledge of indigenous people linked to biological resources, published August 10, 2002.
- Supreme Decree Nº 003-2009-MINAM, that ratifies the approval of the Regulation on Access to Genetic Resources, published on February 7, 2009.
- Supreme Decree Nº 018-2015-MINAGRI, published on September 30, 2015, approves the Regulation for Forestry Management, which include the genetic access regulation of wild flora species.
- Supreme Decree Nº 019-2015-MINAGRI, published on September 30, 2015, approves the Regulation for Wildlife Management, which include the genetic access regulation of wildlife species.

III. National Competent Authorities

The Peruvian Regulation on Access to Genetic Resources (S.D. Nº 003-2009-MINAM) establishes the National Competent Authorities, called *Administration and Enforcement Authorities* for Access to Genetic Resources, and are the follows:

a. Ministry of Agriculture (currently represented by the Peruvian Forestry and Wildlife Service-SERFOR): for genetic resources, molecules, combinations or mixtures of natural molecules, including raw extracts and other derivatives contained in wildland species, such contents may be found in all or part of the plant or animal specimen, including Class Amphibia, and microorganisms. The Ministry of Agriculture evaluates requests for access to genetic resources of wild relatives of species cultivated in coordination with INIA.

b. Peruvian Institute of Agrarian Innovation (INIA): for genetic resources, molecules, combination or mixture of natural molecules, including raw extracts and other derivatives contained in cultivated or domestic species. The content can be found in all or part of the specimen;

c. Ministry of Production – Vice Ministry of Fisheries: for genetic resources, molecules, combination or mixture of natural molecules, including crude extracts and other derivatives contained in the marine and inland water hydrobiological species. The content can be found in all or part of the specimen.

Likewise, the Peruvian Regulation on Access to Genetic Resources states that the Ministry of the Environment-MINAM is the regulatory authority for access to genetic resources; and guides and supervises the management of access to genetic resources; and also constitutes the National Focal Point for the Nagoya Protocol.

In addition, in relation to traditional knowledge (TK) in Peru, the Competent Authority is the National Institute for the Defense of Competition and Protection of Intellectual Property-INDECOPI, which works closely with the Ministry of Culture.

Finally, INDECOPI, and the National Commission against Biopiracy (Comisión Nacional contra la Biopiratería), are the checkpoints for monitoring the utilization of genetic resources.

IV. Procedures for Access to Genetic Resources

The authorization for the access to genetic resources is improved with a contract for access to genetic resources. In addition to the contract for access to genetic resources, exists the genetic material transfer agreement (MTA), which is a simplified contract for transfer of genetic material between *ex situ* conservation centers, based in the country and only for research purposes.

The requirements for the Contracts are:

- Application addressed to the CNA.
- Identification of the provider of the genetic resource (and TK if applicable), generally represented by Research Authorization.
- Research Plan.
- Curriculum vitae of the principal investigator.
- Letter of presentation of each participant of the project.
- Letter of agreement with National Support Institution (according the concept on S.D. Nº 003-2009-MINAM).
- Accessory contracts in accordance with current regulations.
- Prior informed consent of the communities (for the case of access to associated traditional knowledge).
- Payment receipt (if applicable).

The scheme for the analysis and granting of the contracts is (basically) as follows:

IV. Implementation of Nagoya Protocol in Peru

The Nagoya Protocol in Peru is under implementation, by the coordination of the Ministry of the Environment, with the National Competent Authorities, INDECOPI, the Ministry of Culture, among other institutions.

Currently with the Regulations of Forestry and Wildlife Law (S.D. Nº 018-2015-MINAGRI and Nº 019-2015-MINAGRI), the basic taxonomic research was exempted of the contracts for access to genetic resources, complying with the article 8a) of the Nagoya Protocol, in order to facilitate the basic research. The SERFOR includes into the Research Authorizations, compliance clauses in order to secure mutual agreement terms related to this basic research.

Finally, all the Peruvian authorities are working to improve their capacities, principally in terms of negotiation.

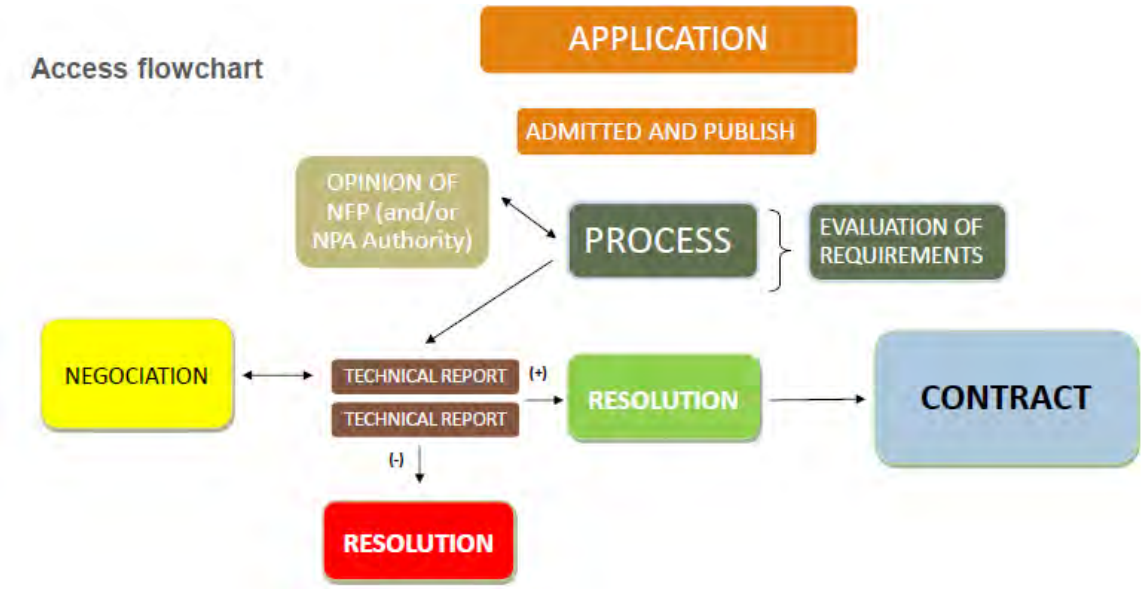

Fig. 21: Access flowchart Peru

9.2 Questions and Answers

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

- In Peru, different competent national authorities manage access procedures, depending on the type of genetic resources sought and used. Peru has three CNAs: The National Forest and Wildlife Service (SERFOR) for wild fauna and flora, the National Institute of Agrarian Innovation (INIA) for cultivated and domestic species and the Ministry of Production (PRODUCE) for hydrobiological marine and freshwater species.
- Peru is bound by the regime on access to genetic resources established by Decision 391 of the Andean Community (CAN), dating from 1996. This Decision is a pioneer regulation applicable to all Andean member countries. It establishes general principles for ABS, as well as specific requirements and procedures. An update of the Decision is underway and is expected to be finalized by 2018. Likewise, Peru has its own regulatory framework, Supreme Decree N ° 003-2009-MINAM, Regulation for access to genetic resources.
- Authorisation from the local community (native and peasant communities according to Peruvian regulation) is required for access to genetic resources from a community and traditional knowledge associated to genetic resources. This authorisation is a requirement of the access procedure requested by the CNAs.
- In addition to CNAs, Peru has established the National Commission Against Biopiracy that works as a checkpoint. Its role is to investigate applications for patent protection in other countries with a link to Peruvian biological resources or associated traditional knowledge.
- The number of access permits granted in Peru reached 90 until 2016, between SERFOR and INIA, however the majority of them were issued for taxonomic purposes only. In application of article 8a) of the Nagoya Protocol, SERFOR implemented a regulation specific for taxonomic research (TR), allowing TR only with research

permits. For that reason, the contracts ranged from 22 (year 2014) to 01 (year 2016). Insight was sought by participants as to why the number of contracts decreased. In response it was clarified that all contracts were for taxonomic purposes only (and the last one concerned natural protected areas).

- Peru is expecting to consolidate its own ABS system and start the issuance of contracts for applied research and commercial purposes by 2018.

9.3 Access Profile

Tab. 6: Access profile Peru

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	yes		ABS -CH
Signatory	yes		ABS -CH
NFP (National Focal Point)	yes		ABS -CH
Contact NFP	00511 611 6000 ext 1340, 1346 mcerdan@minam.gob.pe		ABS -CH
CNA (Competent National Authority)	yes	There are three (03) different CNA, each one responsible for a certain subset of genetic resources. 1. INIA (National Institute for Agrarian Innovation) for cultivated and domestic continental species 2. Ministry of Agriculture through SERFOR (National Forestry and Wildlife Service), for wild continental species and microorganism 3. Underministry of Fishery and Aquaculture (Ministry of Production), for marine and aquatic species For the Traditional Knowledge and Law N° 27811 implementation the Competent Authority is the National Institute for the Defense of Competition and Protection of Intellectual Property (INDECOPI)	Supreme Decree N° 003-2009-MINAM Law N° 27811
Contact CNA	yes	INIA: Dr. Miguel Barandiarán Gamarra Chief jefatura2@inia.gob.pe SERFOR: Mr. John Leigh Vetter Executive Director jleigh@serfor.gob.pe	INIA / SERFOR
CNA Deputy	Not	Not designed yet	--
Contact CNA Deputy	Not	Not designed yet	--

Criteria	Acquired information	Comments	Source
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	yes	INDECOPI (patent office) - implementation of Law 27811 for the protection of TK; Ministry of Culture for broader IPLC policies Peru has a law that establishes a special protection regime, for the collective knowledge of indigenous peoples that is associated to biological resources, within the intellectual property framework.	MINAM web site - ABS and related laws and regulations
ABS law	yes	Nagoya Protocol (ratified by Supreme Decree N° 029-2014-RE) Decision 391 of the Andean Community on ABS	MINAM web site and ABS related laws and regulations
Specific access regulation	yes	Decision 391 of the Andean Community on ABS Supreme Decree N° 003-2009-MINAM;	MINAM web site and ABS related laws and regulations
Specific access procedures (law or any defined process) for non-commercial use	yes	INIA: Facilitated access, through the multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). SERFOR: Facilitated access, through the exception Contract of Access for the basic taxonomic research.	INIA: Supreme Decree Nº 012-2003-PCM SERFOR: Supreme Decrees Nº 018-2015-MINAGRI and N° 019-2015-MINAGRI
English translation for users	yes	Decision 391 of the Andean Community on ABS - http://www.wipo.int/wipolex/en/text.jsp?file_id=223610 There is a translation available for the regulation but I am not able to find the site where it is hosted	WIPO
Visualization of ABS procedure	To be constructed	--	--
Information on access procedure / regulations accessible through weblink	To be constructed	--	--
Access demand form	yes	INIA and SERFOR have their own models of form to access application.	INIA / SERFOR
Specific access demand	no	--	INIA / SERFOR

Criteria	Acquired information	Comments	Source
form for non-commercial purposes			
Online application system	To be constructed	--	--
Compulsory documents for access demand application	yes	INIA and SERFOR have their own requirements according with the Supreme Decree N° 003-2009-MINAM and sectorial normative	INIA / SERFOR
Submission of access application at	three sectorial competent authorities	1. INIA (National Institute for Agrarian Innovation) for cultivated and domestic continental species 2. Ministry of Agriculture through SERFOR (National Forestry and Wildlife Service), for wild continental species and microorganism. 3. Underministry of Fishery and Aquaculture (Ministry of Production), for marine and aquatic species.	Supreme Decree N° 003-2009-MINAM
Access fees	not yet	The amount will be determined in a short time	ABS laws and regulations
Other permits prerequisite to obtain ABS permit	no	• Inside the evaluation process, technical opinion of the Protected Areas Authority (SERNANP) is requested if biological resources are collected from natural protected areas. • Inside the evaluation process, technical opinion of MINAM is requested.	Supreme Decree N° 003-2009-MINAM
IRCC (Internationally Recognised Certificate of Compliance)	not yet	--	--
Have ABS permit(s) been issued in the country?	yes	Since 2009 to 2016, Peru had issued 89 permits (between Contracts and AMT).	INIA / SERFOR
ABS permit(s) issued by	INIA and SERFOR	SERFOR had issued 46 Contracts and INIA, 43 AMT (Agreement of Material Transfer).	INIA / SERFOR
Average timeline (from access demand to permit)	legally it must be 30 business days, with the possibility to extend until 60 business days	The actual average timeline is around 15 months, with cases that had lasted until 2 years or more.	ABS laws and regulations
MAT(s) signed	yes	SERFOR had subscribed 46 contracts of access and INIA, had approved 43 AMT subscribed by the user and ex situ center.	INIA / SERFOR

Criteria	Acquired information	Comments	Source
MAT(s) to be signed with	National Competent Authorities	INIA, SERFOR and the Underministry of Fishery and Aquaculture	ABS laws and regulations
Standard MAT clauses	yes	INIA and SERFOR elaborated their own clauses in negotiation with the user.	INIA / SERFOR
PIC(s) granted	yes	The PIC was granted by INIA and SERFOR through their own Research Authorizations (including SERNANP Authorizations)	INIA / SERFOR
PIC(s) to be granted by	providers of GR, providers of GR contained in biological species, and National Competent Authorities	Until 2016, only SERFOR had supported PICs granted, through the Research Authorization.	INIA / SERFOR

10 Access Procedures of Kenya

Mr. Mukonyi Kavaka Watai, National Chair ABS Committee, Head Bioprospecting, Kenya Wildlife Service

Fig. 22: Mr. Mukonyi Kavaka Watai

10.1 Country Presentation

Kenya has been recognized among the mega diverse rich biodiversity countries in the world with varied biological resources distributed in wide range of ecosystems, from marine, saline lakes, montane, desert like, equatorial rain forest to fresh water. The country is rich in both wild and agriculture based biological resources. These biological resources and associated knowledge are accessed and utilized by wide range of stakeholders ranging from, local communities, academia, industrialist, tourists and ex-situ conservation. Recent survey reveals an increased demand for the country's genetic resource for research and development as seen from the publications and patents granted and assign to major companies in Europe, USA and local research institutions. Regardless of the increased demand of the countries genetic resources for various uses there is a challenge in matching the accrued benefits impact to conservation at the resource provider side. Therefore there is a need for an appropriate framework for the equitable share of resultant benefits between providers and users to promote conservation of species and gene diversity for the present and future generations.

In this regard, Kenya has recognized the importance of its biological resources and established access measures that govern access and utilization of genetic resources. Biological resource access and utilization are governed by the country's supreme law, the constitution and the subsequent national legislations and county laws. Kenya's resource management is devolved at the national and county level and each has rights and obligations in granting various user rights on access and utilization of the genetic resources. The key frameworks governing access to the countries genetic resources include the relevant multi-lateral agreement ratified by the country at the international level, namely the Convention on Biological Diversity (CBD) and its two protocols Nagoya and Cartegena, the International Treaty on Plant Genetic resources for Food and Agriculture's (ITPGRFA), Intellectual property conventions under the WIPO treaty and plant breeders. Specifically Kenya ratified Nagoya Protocol in May 2014. These MEAS are enforced both at the constitution and domesticated under national legislations such as the Environment Management Coordination Act 2015 and its regulation and access and benefit sharing 2006, the Wildlife (Conservation and Management) Act 2013, Forest Act 2016, Seed and plant varied Act 2016, Traditional knowledge and cultural expression Act 2016, Bio safety Act 2012 and Science Technology and Innovation act 2012.

Currently the country does not have a substantive ABS law but access and utilization are governed under the ABS regulation legal notice 160 supported by other relevant laws. The country is in the process of development of a substantive ABS law. There are various stages of access granting process in the country ranging from permitting process, acquisition and export. It is advisable to plan well and understand all the requirements, during the access process that is from proposal development, application, acquisitions and export of the material including the Intellectual property process and technology transfer level. The key requirements include a Prior Informed Consent (PIC) and Mutual Agreed Terms (MAT) and Material Transfer Agreement (MTA) from designated resource providers, research permits from National Council of Science and Technology (NACOST), access permit from NEMA as evidence of grant of PIC, MAT and research permit and export permit from KWS accompanied by Phytosanitary from KEPHIS and for animal department of veterinary services. Genetic resources under Annex 1 are handled by Genetic resource institute (GERRI) and approval for R&D involving genetically modified organisms is by the National bio safety Authority (NBA). The ABS permitting process under different institutions is online, although it has not been integrated. There are efforts being supported by the GIZ-implemented ABS Capacity Development Initiative to create a single window permitting system to promote and facilitate applications thereby creating a favourable environment for R&D.

The country has recognized the ABS based R&D as a major tool to valorize its genetic resources leading to enhanced benefits and therefore it is in the process of establishing the appropriate legal, institutional and policy framework that will attract investments in this subsector and promote conservation and livelihoods of its citizens.

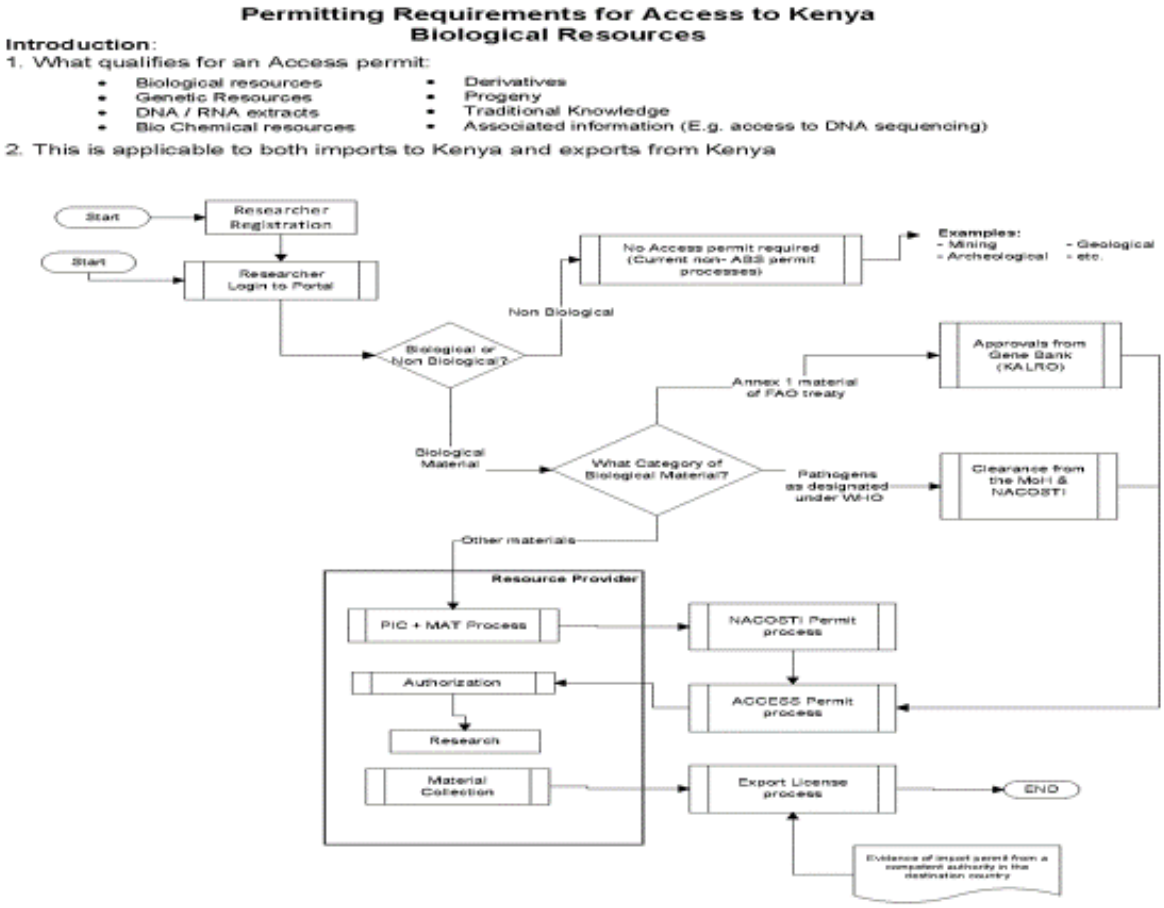

Fig. 23: Flow Chart Kenya

10.2 Questions and Answers

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

- A distinction is made between genetic resources and biological resources. What are the different processes? Kenya's ABS law includes access to intangibles derived from biological or genetic resources. There is no major difference between biological resources or genetic resources as biological resources include the genetic resources. For Kenya, genetic resources include the coded information in the material such as the digital sequence information (DSI). The process includes a pre-application process of PIC, MAT and proposal with the provider, research approvals by the National Council for Science Technology and Innovation (NACOSTI) and approvals for access permits by the National Environmental Management Authority (NEMA). All applications begin by NACOSTI. More details can be obtained on the ABS-CH.
- Once the researcher deposits a strain outside Kenya, how do you control depositories outside of Kenya? Both commercial and non-commercial research is regulated. How can this be controlled practically? It is a challenge. Users need to send back the catalogue numbers of the collection. Kenya is developing a unique identifier system to link in-situ collections with ex-situ and the permitting process. The access and ex-situ repository obligations are covered under PIC, MAT and MTA. The utilization value chain is covered in the contracts and the parties are to comply. Although it is a

challenge where parties deposit various components such as DNA, DNA sequences in databases and genebanks that are later accessed by third parties contravening the agreements. Most of the ex-situ and databases have not established Nagoya instruments for PIC and MAT. Kenyan authorities will monitor this and check whether all obligations in the material transfer agreement have been followed.

- How are intellectual property issues being regulated? Kenya always undertakes IP audit and encourages all projects to develop standard operating procedures (SOPS) which include management of IP issues. Kenya has a strong IP system ranging from patents, copyrights and plant varities. Any IP issues including related technology transfer are regulated in MAT.
- Kenya established an ABS regulation in 2006 which was operationalized in 2008. Since 2009 71 permits have been granted (all non-commercial). Kenya focuses on clear systems of MTA and MAT as agreed upon in the PIC. Initially applications were being published in a gazette notice for feedback but this has been reviewed. Currently Kenya develops in partnership with the GIZ-implemented ABS Capacity Development Initiative an online integrated permitting system that brings together all agencies involved in this process to create a kind of “single window”. This will accelerate and facilitate R&D on Kenyan biological resources. At the same time the country is reviewing its laws specifically the ABS regulations and has also proposed to develop a substantive ABS law to comply with the provisions of the Nagoya Protocol.

10.3 **Access Profile**

Tab. 7:Access profile Kenya

Criteria	**Acquired information**	**Comments**	**Source**
Party Nagoya Protocol	yes		ABS -CH
Signatory	yes		ABS -CH
NFP (National Focal Point)	yes		ABS -CH
Contact NFP	psoffice@environment.go.ke +254 20 273 0808 + 254 20 271 3654		ABS -CH
CNA (Competent National Authority)	yes	National Environment Management Authority (NEMA), for the Grant of ABS permit as evidence of PIC and MAT from the resource providers.	ABS -CH
Contact CNA	dgnema@nema.go.ke +254 020 2101370 +254 020 230 7281 +254 020 2103696		ABS -CH
CNA Deputy	no		
Contact CNA Deputy	no information		
Relevant	no	Competent authorities for IPLCs not designated.	

Criteria	Acquired information	Comments	Source
competent authorities of IPLCs (Indigenous Peoples and Local Communities)			
ABS law	yes	No substantive ABS law yet. This has been proposed, but we have country domestic legislative measures - Kenya Constitution 2010, Environment Management and coordination Act 1999 amendment 2015,Wildlife (Conservation and Management) Act 2013,Seed and plant Variety Act 2012, Protection of Traditional Knowledge and Cultural Expressions Act, 2016.	Ecolex; Kenya Law
Specific access regulation	Yes	The Environmental Management and Co-ordination (Conservation of biological diversity and resources, access to genetic resources and benefit sharing) regulations, 2006. These Regulations concern the conservation of biological diversity in Kenya and the control on access to genetic resources of Kenya.	ABS-CH; Ecolex
Specific access procedures (law or any defined process) for non-commercial use	No	There are procedures as outline in the ABS toolkit. The procedure does not categorize commercial and non commercial. Access follows the steps of negotiating PIC, MAT and MTA from the designated National resource providers and IPLCs, then research permits from NACOSTI and finally an access permit from NEMA. During export, the researcher has to get an export permit from KWS with other additional permits like phytosanitary certificate from KEPHIS and others based on the nature of the genetic resource	KWS website NEMA website NACOSTI website
English translation for users	Yes	English	
Visualization of ABS procedure	yes	A flowchart of access procedure in Kenya exists in ABS Tool Kit, see p. 52 at https://absch.cbd.int/api/v2013/documents/A5F8E9A7-C066-77CC-7446-D188F351F10A/attachments/ABS%20TOOL%20KIT%20FINAL.pdf	ABS-CH
Information on access procedure / regulations accessible through weblink	yes	Access and Benefit Sharing Portal for Kenya: http://meas.nema.go.ke/abs/	ABS-CH, KWS website
Access demand form	yes	At every institution involved in the permitting process: at PIC, MAT and MTA level (KWS), application for at NACOSTI and another application for access permit at	Regulations 2006 (First Schedule), NACOSTI

Criteria	Acquired information	Comments	Source
		NEMA	website KWS website
Specific access demand form for non-commercial purposes	no	Standard form for both commercial and non commercial at all levels	Regulations 2006 (First Schedule), NACOSTI website KWS website
Online application system	under development	All institutions have an online system. Its only that the systems are being integrated into a single window IT based ABS online system	NACOSTI website KWS website NEMA website
Compulsory documents for access demand application	yes	In Kenya we have the PIC, MAT and MTA step, the permit step which involves both the research and access permit then the export step when the material is being exported or imported. All these steps are various access demand applications. 1. Application at the provider, one needs a copy of passport, an affiliation letter from a local institution, a letter of intent, proposal, completed application form, PIC, MAT and MTA. 2. Process of acquiring permits at NACOSTI and NEMA. At NEMA, you require to fill the application form,joint proposal, payment of the access permit, a copy of the Prior Informed Consent, and Mutually Agreed Terms (MAT -which is either MOU or MOA) document signed by the providers and the users .At NACOSTI : Affiliation letter from local counterpart, Letter of Intent and Partnership MOU and Project proposal abstract. The applicant proceeds to apply for researcher's pass or visa stamp issued by the Department of Immigration Services. The Pass is required by NEMA together with letter of affiliation for processing of access permit. http://meas.nema.go.ke/abs/download/Access%20and%20Benefit%20Sharing%20brochure%20final.pdf .Upon export you will fill in export application form at KWS which will be accompanied by other approvals,Phytosanitary certificate from KEPHIS,Biosafety certificate among others	NEMA website ,KWS website
Submission of access application at	National Environmental Management Authority (NEMA)		ABS Regulations 2006
Access fees	yes	To apply for an access permit: - for individual access applicants: 20,000.00 KSh - for corporate applicants: 50,000.00 KSh	ABS Regulations 2006

Criteria	Acquired information	Comments	Source
Other permits prerequisite to obtain ABS permit	yes	In addition to the access permit, the permit holder wishing to export GR outside Kenya is required to execute Material Transfer Agreement (MTA) and to apply for either phyto-sanitary or animal health certificate from KEPHIS or Department of Veterinary Services respectively. http://meas.nema.go.ke/abs/download/Access%20and%20Benefit%20Sharing%20brochure%20final.pdf	Nema website
IRCC (Internationally Recognised Certificate of Compliance)	no	Not yet developed	
Have ABS permit(s) been issued in the country?	yes	71 application and 66 granted	NEMA
ABS permit(s) issued by	National Environmental Management Authority (NEMA)	Access permits are issued by NEMA subject to provision of the following documents: i. Research Clearance Licence from the National Commission for Science, Technology and Innovation (NACOSTI) ii. Prior Informed Consent (PIC) granted to users by resource providers, and iii. An agreement based on MAT between resource provider and users NEMA invites ABS Technical Committee to determine the application taking into consideration the comments from the public and other stakeholders. After approval of the ABS Technical Committee, it recommends to NEMA to issue an access permit. http://meas.nema.go.ke/abs/download/Access%20and%20Benefit%20Sharing%20brochure%20final.pdf	Nema website
Average timeline (from access demand to permit)	timeline defined	NEMA shall, within sixty days of receipt of an application for an access permit, determine the application and communicate its decision in writing to the applicant. Also various demand points at PIC MAT process, NACOSTI and NEMA. About 3 month the whole application process	ABS Regulations 2006
MAT(s) signed	yes	Various MAT and PIC have been signed	KWS and NEMA documents
MAT(s) to be signed with	Provider /user legal entities	They are derived from PIC process and signed as either MOU or MOA between the legal providers and	KWS website NEMA

Criteria	Acquired information	Comments	Source
		users	website NA-COSTI web-site
Standard MAT clauses	yes	A sample MAT format can be found in Appendix II of Kenya's ABS Toolkit .This are subjet to negotiation but vary	Nema web-site
PIC(s) granted	yes	PIC is provided by a lead agency (designated resource provider by the law , local community or private re-source manager. An overview of lead agencies can be found in the ABS Tool Kit (p. 23)	
PIC(s) to be granted by	Designated resource provider (lead agency) and local communities	PIC is provided by a lead agency, local community or private resource manager. An overview of lead agen-cies can be found in the ABS Tool Kit (p. 23) Some time these lead agencies are referred to as other com-petent authorities .	NEMA WEB-SITE,KWS WEBSITE

11 Access Procedures of Costa Rica

Ms. Melania Muñoz García, Technical Office, National Commission for Biodiversity Management, Ministry of Environment and Energy (MINAE), ABS National Focal Point;

Mr. José Alfredo Hernández Ugalde, Technical Office of the Ministry CONAGEBIO, Ministry of Environment and Energy (MINAE)

Fig. 25: Ms. Melania Muñoz García

Fig. 24: Mr. José Alfredo Hernández Ugalde

11.1 Country Presentation

Regulatory framework and procedures to obtain permissions to access genetic and biochemical resources in Costa Rica

National Commission for Biodiversity Management (CONAGEBIO)

Ministry of Environment and Energy

Costa Rica

Costa Rica ratified the CBD in 1994 and signed the Nagoya Protocol in 2011, but the ratification of this Protocol is still in process. Besides that, an ABS regulation is in implementation, and it contains the main NP elements, including Prior Informed Consent and Mutually Agreed Terms between supplier and user (see figure 26):

- Biodiversity Law 7788 (1998)
- General norms to access genetic and biochemical elements and resources of the Biodiversity Decree 31514 (2003)
- Norms to access genetic and biochemical elements and resources in *ex situ* collections Decree 33697 (2007)
- Regulation for the application of administrative sanctions on non-authorized access to genetic and biochemical elements and resources, established in the Biodiversity Law Decree 39341 (2016)

Information about CNA and NFP can be found in ABS-CH and CDB website:

- Competent National Authority. Mrs Angela González Grau (CONAGEBIO)
- ABS Focal Point. Mrs Melania Muñoz García.
- 8J Focal Point. Mrs Alejandra Loría Martínez.

The national legislation established three kinds of permissions:

- Basic research: Activity to investigate, examine, classify or increase existing knowledge over biological elements in general or their genetic or biochemical characteristics in particular, without immediate interest in commercializing its results.
- Bioprospection: The systematic search, classification and research for commercial purposes of new sources of chemical compounds, genes, proteins, and micro-organisms, with real or potential economic value, which are found in biodiversity.
- Commercial use: Occasional or constant use of the biochemical or genetic elements and resources of biodiversity for commercial purposes, without necessarily being preceded by a basic research or bioprospection program as part of the application.

Exclusions:

- Biochemical or genetic material of human origin, which is regulated by General Health Law No. 5395 and related legislation.
- Exchange of biochemical or genetic resources among the indigenous people and local communities, nor to the associated knowledge resulting from their non-profit making practices, uses or customs.
- The provisions of this law do not affect university autonomy in the matter of teaching or researching in the field of biodiversity, except if the research has commercial purposes.

More than 500 permits have been granted by Costa Rica since 2004 (see table 8)

Procedures to grant permission to access genetic and biochemical resources in indigenous territories and traditional knowledge are under development. A participatory process and a consultation must be performed with all indigenous territories to build and validate these norms.

Information and technology development:

- CONAGEBIO website www.conagebio.go.cr
- Virtual platform
    - Access Permits to Genetic and Biochemical Resources of biodiversity.
    - Database and better tracking of the distribution of benefits generated.
    - National Register of Systematic e*x situ* Collections.

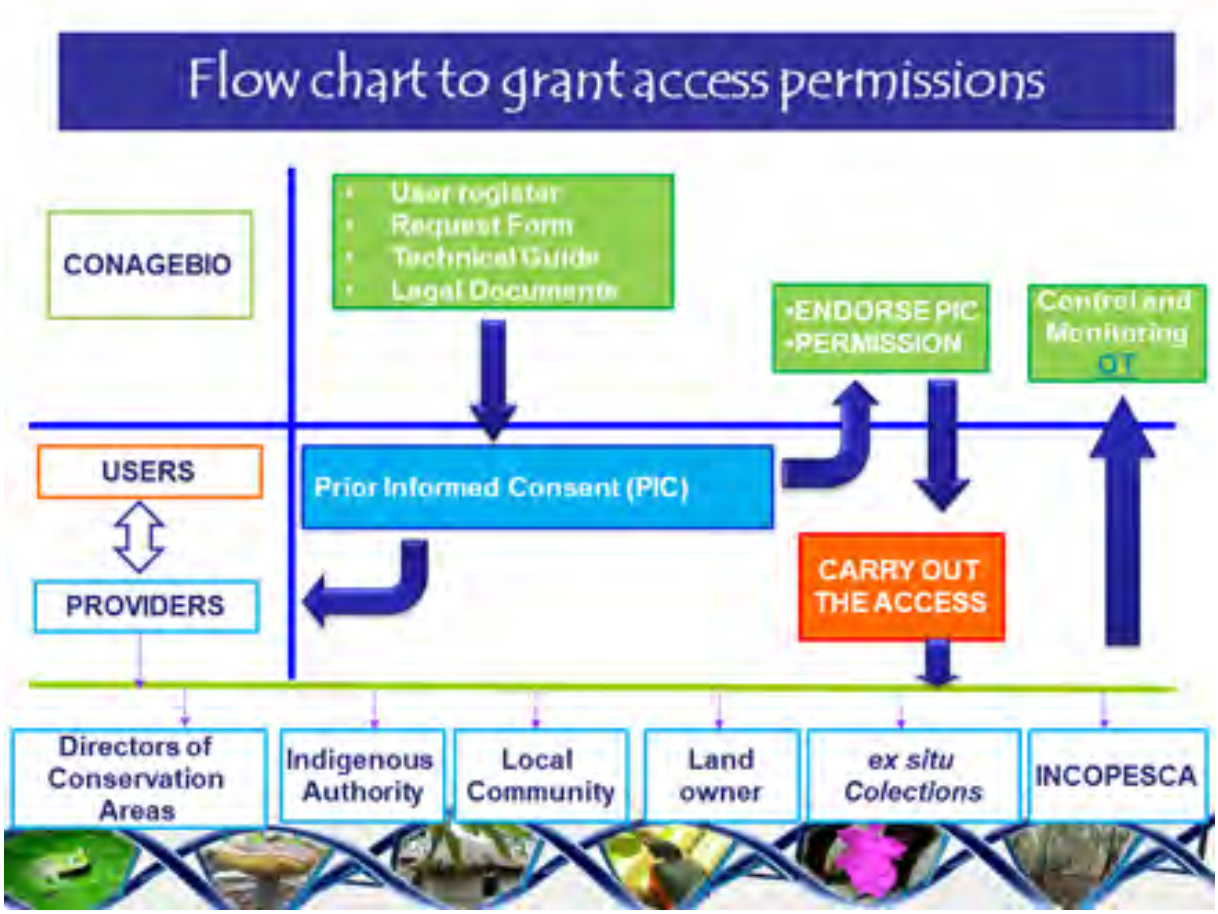

Fig. 26: Flow chart to grant access permissions

Tab. 8: Access permits granted during 2004- August 2017 according to research type

Permits	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Basic Re-search	2	25	26	24	38	32	40	25	37	46	38	50	48	32	463
Bioprospection	2	4	4	6	4	1	11	5	1	10	2	2	4	2	58
Commercial use	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Total	4	29	30	30	42	33	51	30	38	56	40	52	53	34	522

General requirements:

1. Registration form
2. Application form
3. Technical Guideline
4. Copy of the project or fore-project to be carried out.
5. Prior informed consent (PIC) between the applicant and supplier. The prior informed consent and the mutually agreed terms could be reached and negotiated according to the model contract prepared by the Technical Office of CONAGEBio.
6. Photocopy of applicant´s national ID or passport
7. If the applicant and/or the supplier is a juridicial person, Juridical ID and photocopy of national ID or passport of the legal representative.
8. If the applicant(s) is a physical or juridical person residing abroad, he/she will designate a legal representative residing in the country.
9. Documents or representation powers, if needed.
10. Submit, if any, the agreement and/or contract and/or material transfer agreement, subscribed between national or foreign, physical or juridical persons, if they foresee access to the country's genetic and biochemical elements and resources.
11. For basic research or bioprospection, besides what is indicated above, the applicant must submit written formal commitment where it is manifested that, in case of modification of the permit's aims whether for bioprospection or commercial use, the requirements established for each case will be fulfilled.
12. For access to *ex situ* collections, the applicant must sign the code of conduct provided by the Technical Office of CONAGEBIO

Notes:

The signatures of the documents must be authenticated, or the parties may sign in front of the officials of the Technical Office of CONAGEBIO

All documents must be submitted in Spanish

The forms can be completed in the virtual platform available on the website of Conagebio

For occasional or regular commercial use:

Besides what is pointed above, the applicant must include:

1. Description of the commercial use of the genetic and biochemical elements or resources of biodiversity pretended to be extracted or the traditional knowledge associated.
2. General information about the project's economic feasibility.

11.2 Questions and Answers

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

- In Costa Rica there are different types of permits. Permits for (1) basic research, (2) for bioprospection, (3) commercial use. The maximum permit period in Costa Rica is three years. What if the permit is granted for commercial purposes? The maximum permit period is limited to three years but it is possible to apply for an extension before the permit expires.
- How can it be ensured that benefits are fair and equitable? In Costa Rica, ABS contracts need to be endorsed by CONAGEBIO. CONAGEBIO signs a confidentiality agreement and can decide whether it endorses the contract.
- When users enter into contracts with farmers, private reserves or national reserves, how is it possible to address a situation of competition? Further, how can it be ensured that a farmer is sufficiently capacitated to undertake an ABS negotiation? Since the user may choose the contracting party, there is no competition. CONAGEBIO may advise resource providers but is not taking part in the contract negotiation.
- If a resource is available with more than one provider, how can you avoid the situation of competition? There are permits that include more than one provider.
- If the location of access is in more than one conservation area, do you need to ask permission from each conservation area? No, the user can sign a written document and all contracts will be sent to CONAGEBIO. CONAGEBIO may then grant the permit.
- If a user plans to access a particular resource in Costa Rica and requires several providers to obtain sufficient quantity of genetic material, is there any kind of coordination? The researcher may coordinate with different providers and sign only one contract (with several providers). However, it is strongly recommended for the user to enter into a contract with each provider.

11.3 **Access Profile**

Tab. 9: Access profile Costa Rica

Criteria	**Acquired information**	**Comments**	**Source**
Party Nagoya Protocol	no		ABS-CH
Signatory	yes		ABS -CH
NFP (National Focal Point)	yes		ABS -CH
Contact NFP	0050 6 22538416; 0022248664 22341254 melania.conagebio@gmail.com		ABS -CH
CNA (Competent National Authority)	yes		ABS -CH
Contact CNA	00506 22248664 ext 110 agg.conagebio@gmail.com		ABS -CH
CNA Deputy	no	in planning	
Contact CNA Deputy			
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	yes	8j Focal Point Alejandra Loría Martínez Technical Office CONAGEBIO. aloria@minae.go.cr	www.cbd.int Direct contact with ABS Focal Point
ABS law	yes	Biodiversity Law 7788 (1998)	
Specific access regulation	yes	Biodiversity Law 7788 (1998), Executive Decree 31514 (2003), Executive Decree 33697 (2007) and Executive Decree 39341 (2016)	ibidem
Specific access procedures (law or any defined process) for non-commercial use	yes	Biodiversity Law 7788 (1998), Executive Decree 31514 (2003), Executive Decree 33697 (2007) and Executive Decree 39341 (2016)	Ibidem
English translation for users	no	Spanish	Ibidem

Criteria	Acquired information	Comments	Source
Visualization of ABS procedure	yes	www.conagebio.go.cr/Conagebio/public/permisosAccesoInfo.html	ibidem
Information on access procedure / regulations accessible through web-link	yes	tutorial at www.conagebio.go.cr/Conagebio/login.xhtml	ibidem
Access demand form	yes		ibidem
Specific access demand form for non-commercial purposes	yes	the access demand form is the same for basic research, bioprospection and commercialization. Commercialization request has three aditional requisites	ibidem
Online application system	yes	www.conagebio.go.cr/Conagebio/login.xhtml	ibidem
Compulsory documents for access demand application	yes	general requisites for the access permit for GR and biochemicals	ibidem
Submission of access application at	Technical Office of CONAGEBIO	One stop shop / www.conagebio.go.cr/Conagebio/login.xhtml	ibidem
Access fees	no		ibidem
Other permits prerequisite to obtain ABS permit	yes	additional requisites for a permit for occassional and constant economic utilisation	ibidem
IRCC (Internationally Recognised Certificate of Compliance)	no	according to national legislation we issue a Legal Provenance Certificate, but It doesn´t correspont to the one in ABS-CH	ibidem
Have ABS permit(s) been issued in the country?	yes	487 access permits from 2004-2016	ibidem
ABS permit(s) issued by	Technical Office of CONAGEBIO		ibidem

Criteria	Acquired information	Comments	Source
Average timeline (from access demand to permit)	timeline defined	average two to three months	ibidem
MAT(s) signed	yes	MAT is included in PIC document	ibidem
MAT(s) to be signed with	between provider and user - Technical Office of CONAGEBIO countersign these legal instruments		ibidem
Standard MAT clauses	no	only for basic research and bioprospection	ibidem
PIC(s) granted	yes		ibidem
PIC(s) to be granted by	between provider and user - Technical Office of CONAGEBIO countersign these legal instruments		ibidem

12 Access Procedures of Philippines

Ms. Theresa Tenazas, Chief Legal Unit, Biodiversity Management Bureau

Fig. 27: Ms. Theresa Tenazas

12.1 Country Presentation

I.BACKGROUND OF ABS IN THE PHILIPPINES

The Convention on Biological Diversity (CBD), to which the Philippines is a Party, is the first global agreement which focuses on the conservation of biological diversity, the sustainable use of its components, and the fair equitable sharing of benefits arising from the use of genetic resources. The Philippines became a member party on January 6, 1994.

The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity (CBD). It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources. The Philippines became a member-party on December 28, 2015

II.WHAT IS THE LEGAL FRAMEWORK OF ABS IN THE PHILIPPINES?

The Philippines was one of the first countries to come up with a policy on access to biological and genetic resources through Executive Order 247.

E.O. 247 aims to ensure that in the prospecting of biological and genetic resources, these resources are protected and conserved, developed and put to sustainable use for the benefit of the Filipino community.

Thereafter, Republic Act No. 9147 of 2001 otherwise known as the “Wildlife Resources Conservation and Protection Act” was passed on March 19, 2001. The Act provides for the conservation, preservation and protection of wildlife species and their habitats, in order to preserve and encourage ecological balance and biological diversity; it provides furthermore, for the control and supervision of wildlife capture, hunting and trade; finally it provides for supporting and promoting scientific research on the protection of biodiversity.

After years of implementing Executive Order No. 247, the Philippines realized the need to establish specific guidelines on benefit-sharing; parameters to determine the amount of bioprospecting fee and performance bond to be collected from or posted by the researchers, scheme for the payment of royalty, and a well-defined collaborative monitoring system. Thus,

on January 12, 2005, the Joint DA-DENR-PCSD-NCIP A.O. No. 01 of 2005, Guidelines for Bioprospecting Activities in the Philippines was passed.

III. Salient features

- Sets a uniform procedure for evaluating and granting access to biological resources

- Being a joint DENR-DA-PCSD-NCIP issuance, it shall set a uniform procedure for evaluating and granting access to biological resources and avoid the potential problem of inconsistency of bioprospecting regulations for various components of biodiversity under management jurisdiction of different government agencies (DENR, DA and PCSD).
- The National Commission on Indigenous Peoples (NCIP) was added as co-signatory to the joint Administrative Order to ensure that the bioprospecting regulations shall apply to ancestral domains covered by Indigenous Peoples Rights Act (IPRA).
- The guidelines shall apply to research on biological resources for commercial purposes only.
- Redefined “The research, collection, and utilization biological and for purposes of applying the knowledge therefrom solely for commercial purposes”.

IV.SCOPE OF BIOPROSPECTING

- Biological resource found in the Philippines including wildlife, microorganisms, domesticated or propagated species, and exotic species
- All ex-situ collections of biological resources sourced from Philippines except for collections currently accessed under international agreements where Philippines is a party
- All areas including protected areas, private lands, ancestral domain and ancestral lands consistent with Indigenous Peoples Rights Act (IPRA)
- of species listed under the Appendices on International Trade in Endangered Species (CITES) and World Conservation Union Red List, whenever by law.

V.Exempt activities

The Guidelines shall not apply to the following uses of biological resources:

- Traditional use;
- Subsistence consumption;
- Conventional commercial consumption for direct use such as logging or fishing;
- Scientific researches on wildlife under Section 15 of the Wildlife Act;
- Scientific researches on agrobiodiversity; and
- Existing procedures of collection and transport of wildlife species exclusively for commercial or conservation breeding or propagation under Sections 17 and 24 of the Wildlife Act.
    - The development of medicinal plants for traditional or alternative medical use shall be primarily governed by the Traditional and Alternative Medicine Act
- Scientific studies, conducted by researchers with no commercial interests and purely

for academic purposes, using biological resources for taxonomy or solely for the characterization of biological, chemical or physical properties of the biological resources.

VI. INSTITUTIONAL ARRANGEMENTS

Who are the implementing agencies of the joint Bioprospecting Guidelines?

The lead agencies implementing the joint Bioprospecting Guidelines are:

- DENR, through the Biodiversity Management Bureau (BMB), for terrestrial biological resources;
- DA, through the Bureau of Fisheries and Aquatic Resources (BFAR), for aquatic resources;
- PCSD, for biological resources in the Province of Palawan; and,
- NCIP, for matters concerning indigenous peoples (IPs).

VI.Who are the signatories of the Bioprospecting Agreement?

In Accordance with Section 14 of the Wildlife Act, bioprospecting shall be allowed only upon execution of a Bioprospecting Undertaking (BU), between the resource user and the Secretary of the DA and/or DENR, if the biological/genetic resource is a terrestrial and aquatic, respectively.

When the bioprospecting activity is to be conducted in the Province of Palawan, the Chairperson of the PCSD, as authorized by the Council, shall be a co-signatory to the BU;

VII. What is "Bioprospecting Undertaking" or BU

- It refers to the "undertaking" or permit which allows a resource user access to biological resources for bioprospecting purposes
- Contains all the mandatory obligations of the bioprospector to the Philippine government and concerned communities as providers of resource used in the bioprospecting venture.

What is resourse user? It refers to the local or foreign individual, company, organization, institution or entity, either public or private that will utilize biological resources in a given area in the Philippines for bioprospecting purposes.

VIII. How much is Bioprospecting fee?

- For foreign bioprospectors: minimum of $3,000.00 but not more than three times the minimum base on certain criteria.
- For Filipino bioprospectors with no foreign collaborators: 10% of the assessed bioprospecting fee
- For students with no foreign collaborators: 3% of the assessed bioprospecting fee
- No foreign collaborator or investor - …shall mean that the Filipino resource user does not derive assistance or participation of any kind from a foreign collaborator, partner, donor or investor involved directly or indirectly in bioprospecting.
- No commercial interest - … shall mean that the researcher or collector has no track record of involvement in commercial product development or application for intellectual property rights over inventions using or derived from biological resources. Furthermore, the researcher or collector must not have any local or foreign collaborator,

partner, donor or investor involved directly or indirectly in bioprospecting.

IX. Benefit Sharing

1) Payment of Annual Royalties (2% of global sales) in case a product is commercialized to be shared equitably by:

- The Government (thru PCSD, DA, or DENR) to accrue to the Wildlife Management Fund and concerned communities/private land owner where biological material was sourced

2) Annual user's fee for resource provider, communities/private land owner:

- For foreign bioprospectors: $1,000/collection site/ annually

- For local bioprospectors with no foreign collaborators: 10% of $1000 (or $100)/ annually

3) Non-monetary benefits for resource providers

- Equipment for biodiversity inventory and monitoring
- Supplies and equipment for the resource conservation activities
- Technology transfer
- Formal training including educational facilities
- Infrastructure directly related to the management of the area
- Health care
- Other capacity building and support for in-situ conservation and development activities

Is there a difference between commercial and non commercial use?

- The Joint DENR-DA-PCSD-NCIP ADMINISTRATIVE ORDER NO. 1 defined bioprospecting as research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived therefrom solely for commercial purposes only.

X. DURATION OF COLLECTION

- Collection of samples under the BU shall not exceed three (3) years from the date of execution
- Renewable for succeeding periods but not more than three (30 years
- All other terms of the BU shall remain in force until such time when all obligations have been performed.

XI. What are the general guidelines in negotiating for benefit sharing?

1. The resource user shall negotiate with the resource provider through representatives that the resource provider may designate. Decisions of the representative shall be binding on the resource providers unless a formal process of ratification is reserved.

2. When there is more than one (1) provider-group in the area, each provider-group shall designate one (1) representative to the negotiations.

3. Representatives of each provider-group may negotiate collectively or separately with the resource user.

4. However, only one (1) BU shall be executed

XII. What are the general guidelines in negotiating for benefit sharing?

The resource user and providers shall come to an agreement regarding payments of monetary and non-monetary benefits. The negotiated benefits shall be given by the resource user, in the amounts and periods agreed upon, to the government and resource providers, where applicable:

XIII. What are the general guidelines in negotiating for benefit sharing?

Any other commitments made and agreed upon by the resource user and any of the provider-group as conditions for the granting of the PIC shall be separate and independent from the benefits and fees prescribed in the joint Bioprospecting Guidelines.

All payments made by the resource user to any provider-group are non-reimbursable even if no profit is eventually realized from the bioprospecting activity.

XIX. What are the step by step procedures and timeliness for access to genetic resources?

Where to file application?

Depending on the kind of biological resources to be collected and the place of collection, application for a BU may be submitted to any of the implementing agencies:

- BMB for terrestrial resources
- BFAR for aquatic resources
- PCSD and BFAR for aquatic resources in the Province of Palawan, or PCSD and BMB for terrestrial resources in the Province of Palawan, or all three (3) agencies for aquatic and terrestrial resources in the Province of Palawan
- BMB and BFAR for both terrestrial and aquatic resources in all other areas outside the Province of Palawan.

XX. What are the requirements for obtaining a BU?

The following are required prior to the issuance of a BU:

- Letter of intent (LOI)
- Three copies (3) of the research proposal
- Duly accomplished application form
- Company/Institution/Organization/Agency profile
- PIC/FPIC Certificate from resource providers
- Summary of the agreed terms of benefit sharing with resource providers
- Documentary proof of compliance to procurement of PIC/FPIC
- Application/Processing fee of Five Hundred Pesos (Php500.00)
- Others as may be required by the government agency concerned

XXI. What are the Procedures for Securing a BU:

1. Submission of standardized application (w/ proposal) to BMB, BFAR, or PCSD together with:

a) Letter of acceptance from Filipino Collaborator

b) Payment of application fee (P500.00)

2) Submission of Prior Informed Consent Certificate/s

3.) Review of application by BMB, BFAR or PCSD and drafting of the BU

4) Final Evaluation of the bioprospecting application and draft BU by the technical/bio-prospecting committee of respective agency (within15 days).

5.) Endorsement of the BU to the concerned Secretary for approval

6) Approval/disapproval of the BU (within one month)

7) Posting of Performance/Rehabilitation bond in the form of surety bond (25% of of project cost)

8) The Bioprospector may proceed on with the collection activity.

*Payment of Bioprospecting fee shall be in accordance with the agreed schedule as contained in the BU.

XXII. What is the procedure for processing applications for a BU?

Step 1. Submission of application and initial requirements

- Letter of Intent (LOI)
- Duly accomplished application form
- Research proposal
- Company/Institution/Organization/Agency profile
- Application/Processing fee (Php 500.00 only)

Step 2. Initial evaluation

- BMB, BFAR and/or PCSD accepts the application, checks the completeness of the initial requirements, and determines whether the application is covered by the joint Bioprospecting Guidelines. They may consult with their respective or joint Technical Committees in the initial evaluation.
- If the application involves species under the management jurisdiction of DA, DENR and/or PCSD, the concerned agencies shall jointly conduct the initial evaluation. There shall only be one (1) evaluation process and only one (1) BU concluded.

Step 3. Submission of additional requirements

Upon verification that the application is within the coverage of the joint Bioprospecting Guidelines, BMB, BFAR and/or PCSD shall require the applicant to submit the following additional requirements:

- PIC/FPIC Certificate from resource providers following the procedure for obtaining the PIC/FPIC
- Documentary proof of compliance with other relevant requirements under Annex 1 of the joint Bioprospecting Guidelines
- Summary of agreed terms of benefit sharing

- Letter of acceptance from local collaborator
- SEP clearance from PCSD, if bioprospecting is to be conducted in the Province of Palawan only
- Others as may be required by the government agency concerned

Step 4. Preparation of the BU

- Upon verification that all requirements are complete, the concerned agency prepares a draft BU incorporating the terms agreed upon by the resource user and provider.
- In case the bioprospecting activity involves species under multiple jurisdictions, the concerned implementing agencies consolidate all submitted documents, endorse the application to the joint Technical Committee, and jointly prepare the draft BU.

Step 5. Final evaluation by the Technical Committee

- Within fifteen (15) days after receipt of the complete requirements, the respective or joint Technical Committees make a final evaluation of the application as contained in the draft BU.
- The draft BU is forwarded to the appropriate signatories (DENR Secretary, DA Secretary and/or Chairperson of the PCSD) with recommendation for approval or rejection.

Step 6. Decision of appropriate agencies

- Within one (1) month from the submission of the recommendation of the Technical Committee, the appropriate agencies render a decision regarding the approval or rejection of the BU.

Step 7. Posting of rehabilitation/ performance bond

- Within thirty (30) working days after the signing of the BU, the resource user posts a rehabilitation/performance bond in the form of a surety bond, in an amount equivalent to twenty-five percent (25%) of the project cost as reflected in the research budget.

Step 8. Collection of samples

- The resource user may collect samples only after posting the bond. Collection of samples is undertaken in accordance with the collection quota indicated in the BU. Failure to post the bond is a basis for rescission of the BU.

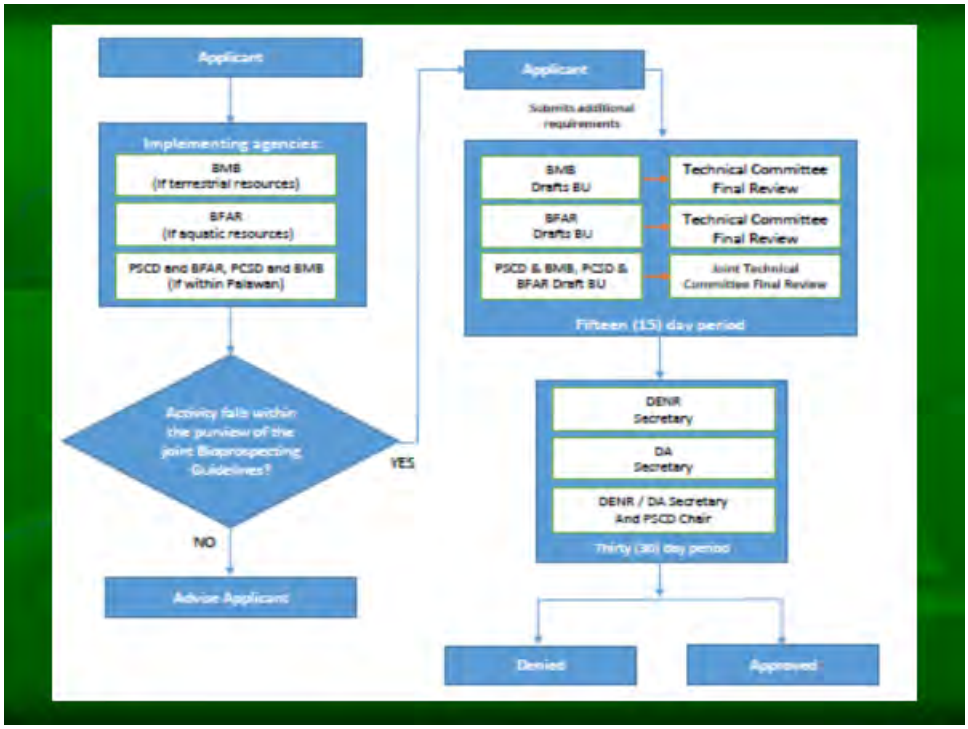

Fig. 28: Flow Chart Philippines

12.2 Questions and Answers

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

- The Philippines formulated a framework legislation on access to genetic resources. Executive Order (EO) No. 247 was issued in 1995 “Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes”. Subsequently, the Department of Environment and Natural Resources (DENR) issued in 1996 the Department Administrative Order No. 96-20 or the Implementing Rules and Regulations of the EO. EO 247 is one of the important national instruments for addressing the interests of the government, as well as those of local and indigenous communities, in relation to benefit-sharing from the use of biodiversity. Later on, to address the restrictive approach of EO 247, Joint DENR-DA-PCSD-NCIP Administrative Order No. 01 entitled *“*Guidelines for Bioprospecting Activities in the Philippines*”* was issued. The joint guidelines establish a more comprehensive and effective mechanism to regulate bioprospecting activities and also responds to recent developments such as the enactment of the Wildlife Resources Conservation and Protection Act or R.A. 9147 of 2001.
- How is benefit-sharing negotiated in the Philippines? The user shall negotiate with the provider through a representative that the provider may designate.
- Is it possible to make an online application to access genetic resources in the Philippines? An application can be made online however, due to the volume of the documents involved and since translation is not yet available in other languages, the user is encouraged to apply in person or through the chosen local counterpart chosen. It is obligatory to have a local counterpart if you want to conduct research and development on genetic resources in the Philippines.

- Free prior informed consent is operational in the Philippines. Users need to obtain free prior informed consent from indigenous local communities before undertaking bioprospecting activities.
- How long does it take from handing in an application for access to genetic resources until final approval? The timeline is around thirty days.

12.3 Access Profile

Tab. 10: Access profile Philippines

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	yes	December 28, 2015	ABS -CH
Signatory	no		ABS -CH
NFP (National Focal Point)	yes		ABS -CH
Contact NFP	pawbdir@yahoo.com bmb@bmb.gov.ph munditalim@yahoo.com +639178033778		ABS -CH
CNA (Competent National Authority)	yes	these are the entities identified under the Joint Department of Environment and Natural Resources (DENR) - Department of Agriculture (DA)-Palawan Council for Sustainable Development (PCSD) and National Commission on Indigenous Peoples (NCIP) Administrative Order No. 1, series of 2005"Guidelines for Bioprospecting Activities in the Philippines (see Section 6 of the JAO). (http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006)	Administrative Order No. 1, series of 2005 "Guidelines for Bioprospecting
Contact CNA	wrd.enforcement@bmb 006329258953		
CNA Deputy	yes		
Contact CNA Deputy	wrd.enforcement@bmb 006329246031 – ext. 224		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	yes	National Commission for Indigenous Peoples	Administrative Order No. 1, series of 2005 "Guidelines

Criteria	Acquired information	Comments	Source
ABS law	yes	Executive Order 247 Bioprospecting Law of the Philippines Wildlife Resources Conservation and Protection Act (Republic Act No. 9147) http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/republic-acts/republic-acts-1997-2006	Faolex/BMB website
Specific access regulation	yes	Joint Implementing Rules And Regulations (IRR) Pursuant To Republic Act No. 9147 (2004) (http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006) Joint DENR-DA-PCSD-NCIP Administrative Order No. 1 of 2005 prescribing Guidelines for Bioprospecting Activities in the Philippines (http://ex-twprlegs1.fao.org/docs/pdf/phi93259.pdf) These bioprospecting guidelines set rules governing the implementation of the Wildlife Act, and other relevant laws that will protect indigenous and local communities with regard to collection, use of biological and genetic resources including wildlife, microorganisms, domesticated or propagated species and exotic species, and equitable sharing from these resources. (http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006)	BMB website
Specific access procedures (law or any defined process) for non-commercial use	yes	ection 15 of the Joint DENR-DA-PCSD Administrative Order No. 01 "Joint Implementing Rules and Regulations of pursuant to Republic Act 9147 (Wildlife Resources COnservtion and Protection Act) provides that collection and utilization of biological resources for scientific research and not for commercial purposes shall be allowed upon execution of an undertaking/agreement with and issuance of a gratuitous permit. (http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao); Scientific studies, conducted by researchers with no commercial interests and purely for academic purposes, using biological resources for taxonomy or solely for the characterization of biological, chemical or physical properties of the biological resources, shall not be covered by the Guidelines but under Sec. 3.2 of the Joint DENR-DA-PCSD-NCIP Administrative Order No. 01. (http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao) and (http://www.denr.gov.ph/component/content/article/3139.html)	Administrative Order No. 1, series of 2005 "Guidelines
English translation for users	yes	Filipino, English	Faolex
Visualization of ABS procedure	yes	http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao	

Criteria	Acquired information	Comments	Source
Information on access procedure / regulations accessible through web-link	yes	http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006 ;	
Access de-mand form	yes	http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006	
Specific ac-cess demand form for non-commercial purposes	yes	letter of Intent	Administra-tive Order No. 1, series of 2005 "Guidelines for Bio-prospecting Activities in the Philip-pines
Online appli-cation system	yes	DENR has developed a Frontline Services Transaction Systems (FSTS). FSTS will provide a facility for the ap-plicants, to be able to submit their documentary requirements ONLINE. The FSTS aims to provide streamlined and standardized work-flows in the delivery of Frontline Services of the DENR. With this, the system will enable the agency to: monitor actual service levels of frontline processing; and, stand-ardize the processing frontline applications across DENR. See weblink: http://www.denr.gov.ph/component/con-tent/article/3139.html	

Criteria	Acquired information	Comments	Source
Compulsory documents for access demand application	yes	For Bioprospecting purposes: PIC is to be secured through the following procedure: a) Notification (resource user applicant shall notify the IPs, LGUs, PAMB, private landowner or other relevant agencies concerned through a letter of intent indicating therein that s/he intends to undertake bioprospecting within their particular areas. The letter of intent which must be submitted together with a copy of the research proposal, which must fully disclose the activity(ies) to be undertaken, and that the application for BU has been filed; b) Sector consultation c) Issuance of PIC certificate For scientific research: (1) For a foreign entity/instituion/individual or Filipino citizen affiliated with a foreign insitution, a Memorandum of Agreement (MOA) shall be executed with the DENR and a Gratutitous Permit may be issued whenever necessary: Requirements are as follows: (a) Research/project proposal; (b) Endorsement letter from the Head of the Institution; or in the case of an individual researchers, from a recognized expert or a research instituion or a conservation organization; and, (c) in case collection of wildlife is necessary, prior clearance from the affected communities, i.e. concerned LGUs, recognized head of indigenous people in accordance with RA 8371, or Protected ARea Management Board , shall be required for the issuance of Gratuitous Permit. (2) For purposes of thesis of students affiliated with local and academic institutions and other government initiated or implemented research or scientific projects, issuance of Gratuitous Permit by concerned DENR Regional Office shall be sufficient, subject to the following requirements: (a) Research/project proposal; (b) Endorsement letter from the concerned Dean; or in the case of an individual researchers, from a recognized expert or a research instituion or a conservation organization; and, (c) in case collection of wildlife is necessary, prior clearance from the affected communities, i.e. concerned LGUs, recognized head of indigenous people in accordance with RA 8371, or Protected ARea Management Board . http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006	Joint DENR-DA-PCSD-NCIP Administrative Order No. 01, series of 2005 Section 4 of Department Administrative Order 2004-55

Criteria	Acquired information	Comments	Source
Submission of access application at	Department of Agriculture (DA) through Bureau of Fisheries and Aquatic Resources (BFAR) for aquatic, Department of Environment and Natural Resources (DENR) through Biodiversity Management Bureau (BMB) if terrestrial Philippine Council for Sustainable Development (PCSD) if in resource is located	As provided for in the Joint DENR-DA-PCSD Administrative Order No. 01 "Joint Implementing Rules and Regulations of pursuant to Republic Act 9147 (Wildlife Resources Conservation and Protection Act)	Guidelines
Access fees	yes	The resource user shall pay the amount of five hundred pesos (PhP 500), upon filing of the application, to each of the appropriate implementing agencies, to cover processing costs. Minimum bioprospecting fee of US$3000 for each bioprospecting undertaking (may increase to up to 9000€ under certain conditions e.g. if the accessed species is rare) (http://extwprlegs1.fao.org/docs/pdf/phi93259.pdf) Gratuitous Permit - PhP100 (http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006)	Guidelines
Other permits prerequisite to obtain ABS permit	yes	Exportation of biological resources shall be subject to applicable CITES rules and regulations on exportation and other rules and regulations. (http://extwprlegs1.fao.org/docs/pdf/phi93259.pdf) Possibly a transport permit for transport of GR within the country. Wildlife collectors permit Wildlife farm/culture permit (http://extwprlegs1.fao.org/docs/pdf/phi157501.pdf) (http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006)	Regulations and Guidelines
IRCC (Internationally Recognised Certificate of Compliance)	no		ABS-CH
Have ABS permit(s) been issued in the country?	yes	For scientific research under Executive Order 247, there are Memorandum of Agreements executed with various foreign and local institutions/organizations and issuance of Gratutitous Permit as necessary.	

Criteria	Acquired information	Comments	Source
ABS permit(s) issued by	Department of Agriculture and monitored by Bureau of Fisheries and Aquatic Resources		
Average timeline (from access demand to permit)	timeline defined	Decision to deny or grant shall be made within 30 days from submission of the Technical Review Committee to the proper signatory (see section 4.2 of DAO 2004-55 and section Chapter 3, Section 8 of Joint DENR-DA-PCSD-NCIP AO No. 01) (http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006)	
MAT(s) signed	yes	this is included in the Bioprospecting Undertaking	
MAT(s) to be signed with	Bioprospecting Undertaking holder and third party recipient		
Standard MAT clauses	yes		
PIC(s) granted	yes	yes, clearance(s)/endorsement(s)/Prior Informed Consent (PIC) Certificate , Free and Prior Informed Consent (FPIC) Certificate are obtained from proper authorities/body(ies) with management jurisdiction over the proposed collection site(s), i.e. head of Indigenous Cultural Communities/Indigenous Peoples in cases where the collection will be undertaken within ancestral domain/lands; concerned Local Government Units (LGU)/Municipal or City Mayor, if the collection will be undertaken within the territorial jurisdiction of a municipality/city but outside a protected areas; and/or Protected Area Management Board (PAMB), if the collection will be undertaken within a protected area. http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006	guidelines
PIC(s) to be granted by	local community	The resource user shall secure the prior informed consent of the concerned resource providers and Free and Prior Informed for Indigenous Peoples/Indigenous Cultural Communities , Protected Area Management Boards, LGUs, private individuals or other agencies having special jurisdiction over specific areas under existing laws, see Section 13 (Guidelines for prior informed consent) of the Joint DENR-DA-PCSD-NCIP Administrative Order No. 01(http://ex-twprlegs1.fao.org/docs/pdf/phi93259.pdf) (http://www.bmb.gov.ph/elibrary/mainmenu-policies-52359/dao/denr-administrative-orders-1997-2006)	guidelines

13 Access Procedures of South Africa

Ms. Lactitia Tshitwamulomoni, Biodiversity Officer Control BABS Policy Development and Implementation, Department of Environmental Affairs, ABS National Focal Point;

Mr. Nomusa Mbuyazi, Biodiversity Officer, Department of Environmental Affairs

Fig. 30: Ms. Lactitia Tshitwamulomoni

Fig. 29: Mr. Nomusa Mbuyazi

13.1 Country Presentation

Summary of the presentation on access procedures of South Africa's framework legislation & associated regulations on Bioprospecting, Access & Benefit Sharing.

South Africa is the 3rd most biodiverse country in the world, it occupies 2% of the world's land area. It consists of 15% of the world's coastal marine species, 10 % of the wold's plant species and 7% of the world's reptiles, birds and mammals. South Africa became party to Nagoya Protocol since 12 October 2014 when the Protocol entered into force and deposited ratification instrument on 10 January 2013 and the signature was deposited on 11 May 2011.

The Bioprospecting, Access and Benefit Sharing (BABS) Regulations, 2008 made under the National Environmental Management Biodiversity Act (NEMBA), Act 10 of 2004 entered into force on 1 April 2008 which have since been amended. The BABS Amendment Regulations came into force on 19 May 2015 and prescribe the notification process for the discovery phase of bioprospecting involving any indigenous genetic and biological resources contemplated in section 81A (2) of the Act and further prescribe the permit system set out in Chapter 7 of the Act insofar as that system applies to bioprospecting involving any indigenous genetic and biological resources or export from the Republic of any indigenous genetic and biological resources for the purpose of bioprospecting or any other kind of research. In addition, the BABS Amendment Regulations set out the form and content of, and requirements and criteria for benefit-sharing and material transfer agreements and the administration process of the Bioprospecting Trust Fund.

The Department of Environmental Affairs is the Competent National Authority and the Focal

Point for ABS. According to the BABS Regulations 2015, the permit may be applied by or granted to a juristic person registered in terms of SA law, a natural person, who is a SA citizen or a permanent resident of SA or a non-juristic or natural person jointly with a juristic or natural person in terms of SA law. The issuing authority must consider & decide on any permit application or notification within 120 working days after the receipt of such an application, if satisfied that all the prescribed & requested information has been submitted.

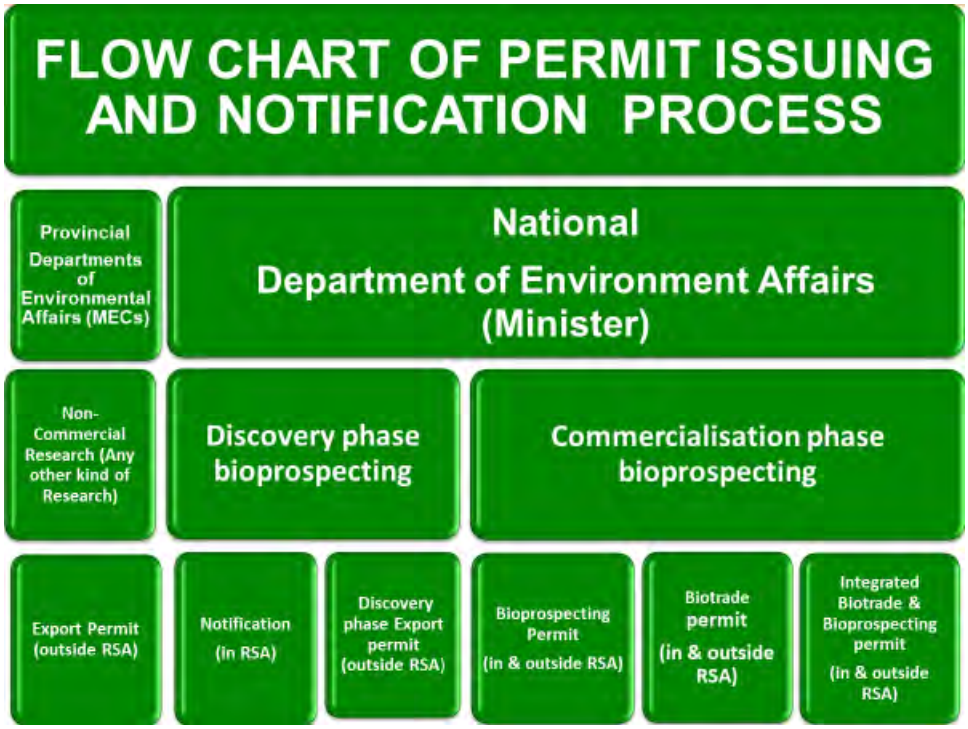

Fig. 31: Flow Chart South Africa 1

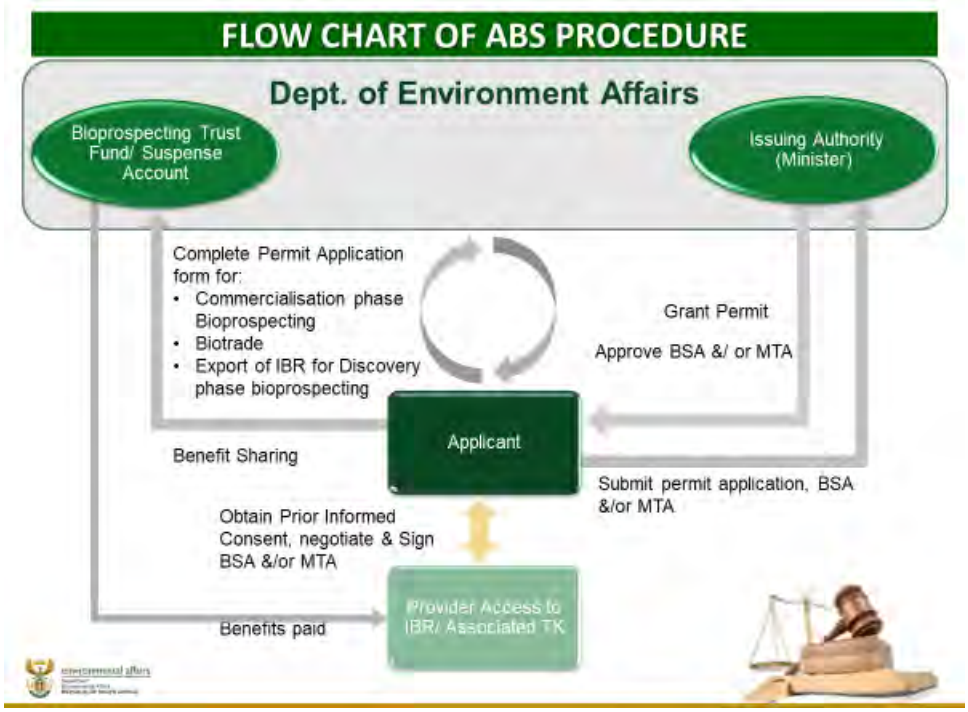

Fig. 32: Flow Chart South Africa 2

13.2 Questions and Answers

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

- South African law has a very wide definition of bioprospecting. The Biodiversity Act defines “indigenous biological resource” to include any living or dead organism of an indigenous species, any genetic material or derivatives of such organisms, or any chemical compounds and products obtained through use of biotechnology that have been altered with genetic material or chemical compounds found in use of their genes or biochemicals. It was enquired at what point a South African indigenous biological resource such as *Hoodia* falls outside the scope of ABS when it has been obtained in a country outside of South Africa. As long as the resource itself can be traced back to South Africa, it falls within the scope and is covered by South African ABS legislation. The issue of controlling access however is not yet operationally addressed, because there are no practical case studies.
- While it is useful to clearly differentiate between genetic resources and associated traditional knowledge, the line is not always clear-cut. For example, traditional knowledge may be used traditionally as a spice, but it may never have been used as a fragrance. If possible national ABS systems should define what falls under genetic resources and what falls under traditional knowledge. South African ABS legislation provides mechanisms to deal with genetic resources only and also to deal with genetic resources and associated traditional knowledge.
- What is not always clear is whether the material is used as commodity or genetic resource. The species may be sold as a commodity, but if research and development is undertaken on this resource, it falls within the scope of the Nagoya Protocol. It was put forward by participants that one way to address this issue is to make a declaration that the resource is explicitly meant for trade purposes and if the buyer aims to undertake research and development, he / she is obliged to comply with the obligations of the Nagoya Protocol.

13.3 **Access Profile**

Tab. 11: Access profile South Africa

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	yes	Since 12 October 2014 when the Protocol enters into force. Deposited ratification instrument on 10 January 2013	ABS -CH
Signatory	yes	Deposited signature on 11 May 2011	ABS -CH
NFP (National Focal Point)	yes	National Department of Environmental Affairs	ABS -CH
Contact NFP	Ms. Lactitia Tshililo Tshitwamulomoni +2712 399 9611 ; lmabadahane@environment.gov.za		ABS -CH
CNA (Competent National Authority)	yes	National Department of Environmental Affairs	ABS -CH
Contact CNA	National Department of Environmental Affairs +27 12 399 9611/8917/9612/9590; BABS@environment.gov.za	Postal address: Private Bag X447, Pretoria 0001. Physical address: 473 Steve Biko street, Arcadia, Pretoria	ABS -CH
CNA Deputy	yes		DEA Website
Contact CNA Deputy	Mr Ntambudzeni Nepfumembe +2712 399 9612; Nnepfumembe@environment.gov.za		DEA website
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	yes	National Department of Science and Technology	DST website
ABS law	yes	National Environmental Management: Biodiversity Act 2004 Chapter 6 of the National Environmental Management: Biodiversity Act (Act no. 10 of 2004) regulates the exploration of biodiversity for commercially valuable indigenous genetic and biological resources and associated traditional knowledge and it came into force on 1 January 2006.	ABS-CH

Criteria	Acquired information	Comments	Source
		The legislation protects the interests of certain stakeholders; outlines the requirements of material transfer and benefit sharing agreements; establishes the Bioprospecting Trust Fund; and provides for the exemption of certain activities or indigenous biological resources from the legislation.	
Specific access regulation	yes	The Bioprospecting, Access and Benefit Sharing (BABS) Regulations, 2008 made under the National Environmental Management Biodiversity Act (NEMBA), Act 10 of 2004 entered into force on 1 April 2008 which have since been amended. The BABS Amendment Regulations came into force on 19 May 2015 and prescribe the notification process for the discovery phase of bioprospecting involving any indigenous genetic and biological resources contemplated in section 81A (2) of the Act and further prescribe the permit system set out in Chapter 7 of the Act insofar as that system applies to bioprospecting involving any indigenous genetic and biological resources or export from the Republic of any indigenous genetic and biological resources for the purpose of bioprospecting or any other kind of research. In addition, the BABS Amendment Regulations set out the form and content of, and requirements and criteria for benefit-sharing and material transfer agreements and the administration process of the Bioprospecting Trust Fund.	https://www.environment.gov.za/projectsprogrammes/babs_clearinghouse
Specific access procedures (law or any defined process) for non-commercial use	yes	Applicant is required to apply for export permits for research other than bio prospecting. These permits falls under non-commercial use and are issued by Provincial Authorities.	ABS-CH
English translation for users	yes	All eleven South African official languages which includes English	DEA website
Visualization of ABS procedure	yes	See South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework Guidelines for Providers, Users and Regulators and associated Posters and Animated video clip	ABS-CH
Information on access procedure / regulations accessible through weblink	yes	https://www.environment.gov.za/sites/default/files/legislations/nemba10of2004_babsregulations_amendments.pdf	DEA website

Criteria	Acquired information	Comments	Source
Access demand form	yes	https://www.environment.gov.za/sites/default/files/docs/forms/annexure5_biosprospectingpermitorbiotradepermit.pdf	ABS-CH
Specific access demand form for non-commercial purposes	yes	https://www.environment.gov.za/sites/default/files/docs/forms/annexure3_exportpermitforresearch_thanbiosprospecting.pdf	ABS-CH
Online application system	no	South Africa is currently working on creating the online permit application system and the information will be available as soon as the system is up and running.	
Compulsory documents for access demand application	yes	The completed and signed application form must be accompanied by Material Transfer Agreement (Annexure 11) and Benefit Sharing Agreement (Annexure 12); Project Proposal/Summary/ Business summary, Certified copy of Identification Document, Community Resolution, Proof of Payment of non-refundable Permit Application fee.	ABS-CH
Submission of access application at	DEA	All applications must be submitted to National Department of Environmental Affairs via email address: BABS@environment.gov.za or hand delivered at 473 Steve Biko street, Arcadia, Pretoria 0001.	ABS-CH
Access fees	yes	Annexure 4 of the BABS Amendment Regulations(2015) sets out the prescribed fees, which are non-refundable	ABS-CH
Other permits prerequisite to obtain ABS permit	yes	In order for permit to be issued, the applicants must comply with the relevant laws and legislations and obtain all relevant permits such as harvesting and collection permits and CITES permit that are issued by the relevant provincial authorities.	DEA website
IRCC (Internationally Recognized Certificate of Compliance)	yes	To date, South Africa has published 3 IRCCs.	ABS-CH
Have ABS permit(s) been issued in the country?	yes	Since the coming into force of the BABS regulations in 2008, South Africa has issued 55 permits.	DEA website
ABS permit(s) issued by	Minister	All permits are approved by the Minister who delegates signing of the issued permit to the Director-General of the Department of Environmental Affairs (DEA)	ABS-CH
Average timeline (from access demand to permit)	Timeline defined	A permit could be issued in 120 working days if all the permit application requirements are met, sufficient information is provided for the issuing authority to make a decision and there is no queries from the issuing authority.	ABS-CH

Criteria	Acquired information	Comments	Source
MAT(s) signed	yes	The Benefit Sharing and Material Transfer Agreements must be approved and signed by the Minister of Environmental Affairs.	ABS-CH
MAT(s) to be signed with	Access Providers	Indigenous communities (communal land owner or traditional knowledge holder, private landowners, state-owned land	ABS-CH
Standard MAT clauses	yes	Standard Benefit-Sharing agreements for varying cases are provided in the annex of the 2015 BABS Amendment Regulation	ABS-CH
PIC(s) granted	Access Providers	Indigenous communities (communal land owner or traditional knowledge holder, private landowners, state-owned land	ABS-CH
PIC(s) to be granted by	Minister	The applicant must provide documentary proof that PIC was granted by the Access Provider and TK Holders, thereafter, the Minister approve issuance of a permit	ABS-CH

14 Access Procedures of Australia

Mr. Ben Phillips, Director Protected Areas Policy and Planning, Australian Government Parks Australia, ABS National Focal Point

Fig. 33: Mr. Ben Phillips

14.1 Country Presentation

The federal system of government in Australia means that responsibility for granting access to genetic resources can sit within the jurisdiction of national and sub-national levels of government. The Australian Government has had legislation regulating access to genetic resources within its jurisdiction since 2005. The stated purposes of the legislation are important – importantly, the purposes include providing certainty and minimise administrative cost as well as ensuring the equitable sharing of benefits arising from the use of genetic resources. Permits are given for access if there is a benefit-sharing agreement between the user and the provider of the resource and if access is ecologically sustainable. The time required to process a permit does depend on the complexity of the permit, but Australia generally can issue a permit in under one week. The benefit sharing agreement comes in two forms. The first is simple with standard requirements binding the user to non-commercial use and reporting conditions, the second is a more expansive contract which can allow for commercial use and corresponding benefit sharing requirements.

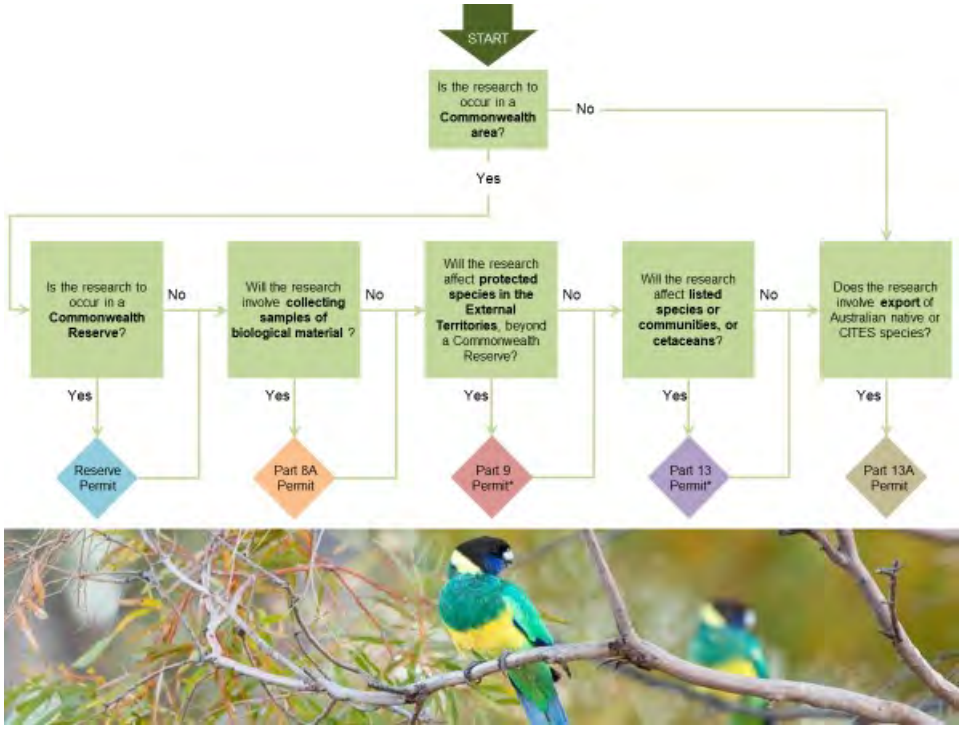

Fig. 34: Flow Chart Australia

14.2 Questions and Answers

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

- In comparison to many other national ABS systems, there is no obligation to have a local counterpart to conduct research and development on genetic resources in Australia.
- With respect to future steps, there is an intention in Australia to ratify the Nagoya Protocol. Australia must have all measures in place to implement obligations before ratification. Australia would need to make some amendments in its legislation particularly on the user side and to take more account of traditional knowledge.
- Different states are access providers. The Australian government does not have jurisdiction over the resources in the different states. Each state has different rules. There are nine governments who could potentially be established as CNAs. A single point of contact (“super CNA”), a role to be played by the Australian Government, would be preferred by many actors.
- Like in Brazil, the entry into the national ABS regime is very easy. Australia aims to encourage research for knowledge, understanding and innovation. It focuses on legal certainty, further reducing transaction costs and flexibility.
- A commercial benefit sharing agreement is fully negotiable. A model of a standard commercial legal agreement exists.
- Regarding permit approval, up to 5 permits may be required to conduct research and development in Australia. The user will not receive an ABS permit if another requisite permit is missing.

14.3 **Access Profile**

Tab. 12: Access profile Australia

Criteria	Acquired information	Comments	Source
Party Nagoya Protocol	no		ABS -CH
Signatory	yes		ABS -CH
NFP (National Focal Point)	yes		ABS -CH
Contact NFP	CBDAustralia@environment.gov.au +61 2 6274 2010		ABS -CH
CNA (Competent National Authority)	not in the terms of the Nagoya Protocol	Competent national authorities as described in the Bonn Guidelines - relevant authorities to grant access - are listed by jurisdiction at http://www.environment.gov.au/topics/science-and-research/australias-biological-resources/access-biological-resources-states-and	ABS -CH
Contact CNA	Yes		CNA
CNA Deputy	Yes		CNA
Contact CNA Deputy	BenParksPolicy.Phillips@environment.gov.au		
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	Under development	Relevant authorities will depend on geographic location and the relevant legal arrangements - authorities may include land councils, native title holders, Indigenous association or others.	
ABS law	Yes	Biodiscovery Act 2004 (2014) (http://extwprlegs1.fao.org/docs/pdf/qs46674.pdf) Biological Resources Act 2006 (http://extwprlegs1.fao.org/docs/pdf/nt75738.pdf)	Faolex
Specific access regulation	yes	Environment Protection and Biodiversity Conservation Regulations 2000 (see Part 8A - Access to biological resources in Commonwealth areas). These Regulations implement provisions of the Environment Protection and Biodiversity Conservation Act 1999 and CITES.	Faolex
Specific access procedures (law or any defined process) for non-commercial use	Yes	The Environment Protection and Biodiversity Conservation Regulations 2000 (2016) distinguish between access to biological resources for commercial and non-commercial purposes (http://extwprlegs1.fao.org/docs/pdf/aus25399.pdf)	Regulations

Criteria	Acquired information	Comments	Source
English translation for users available	Yes	English	
Visualization of ABS procedure	yes		
Information on access procedure / regulations accessible through weblink	yes	http://www.environment.gov.au/topics/science-and-research/australias-biological-resources	
Access request form	yes	http://www.environment.gov.au/system/files/pages/e3584028-d083-4aec-acdd-c0aa635a529f/files/part-8a-application-form.doc	
Specific access demand form for non-commercial purposes	Yes	http://www.environment.gov.au/topics/science-and-research/australias-biological-resources/permits-%E2%80%93-accessing-biological-resourc-1	
Online application system	Yes	From 2018 - currently submission to grm@environment.gov.au	
Compulsory documents for access demand application	yes	http://www.environment.gov.au/system/files/pages/e3584028-d083-4aec-acdd-c0aa635a529f/files/stat-dec.doc	
Submission of access application at	Name of institution	Department of Environment and Energy	
Access fees	commercial only	$50 for commercial permit	
Other permits prerequisite to obtain ABS permit	yes if required	Any relevant access document (for example - permit to collect specimens in a National Park) required by law.	
IRCC (Internationally Recognised Certificate of Compliance)	no	Existing permits would be IRCC, on provision to ABS-CH following Australia's ratification of the Protocol.	ABS -CH
Have ABS permit(s) been issued in the country?	Yes	http://www.environment.gov.au/resource/list-permits-issued	

Criteria	Acquired information	Comments	Source
ABS permit(s) issued by	Minister (or delegate)	Ministries in Australia are called "Departments"	Regulations
Average timeline (from access demand to permit)	timeline defined	Allow 10 working days	Regulations
MAT(s) signed	yes	All permits have MAT - whether in a commercial contract, or the non-commercial statutory declaration undertaking to provide research results, and to lodge taxonomic duplicates with national institutions.	
MAT(s) to be signed with	Access provider, defined in regulations - dependent on existing property rights to grant access.		
Standard MAT clauses	yes	see model contract at http://www.environment.gov.au/topics/science-and-research/australias-biological-resources/permits-%E2%80%93-accessing-biological-resourc-0	
PIC(s) granted	yes	http://www.environment.gov.au/resource/list-permits-issued	
PIC(s) to be granted by	Minister (or delegate)		

15 Synthesis of Issues raised in the Q&A Sessions

A number of key issues were raised in the Q&A sessions, including the following:

- In most countries a local counterpart is a prerequisite for foreigners wishing to undertake research on genetic resources and / or associated traditional knowledge (aTK) in the provider country. Information on potential collaboration partners is available in many countries. Further, many ABS systems distinguish between access for commercial and non-commercial purposes.
- What constitutes PIC and MAT differs depending on the national context. Under the Brazilian law for example, access to genetic heritage does not require PIC as such but is subject to an electronic registration system (the National System for the Management of Genetic Heritage and Associated Traditional Knowledge). According to the Biodiversity Law in Costa Rica on the other hand, PIC includes MAT (PIC (Costa Rica) = PIC + MAT).
- It is key to involve and empower local communities in ABS processes. In some countries (e.g. Peru) consent from the local community is required to access not only traditional knowledge but also genetic resources held by local communities. A key question that arose in this context related to ownership issues in the case where the traditional knowledge is held by several communities. Examples from countries documenting traditional knowledge were also briefly introduced (e.g. the Indian Traditional Knowledge Digital Library).
- Intellectual property rights (IPR) play a key role for ABS. ABS regimes address IPR to varying degrees. Generally, intellectual property aspects are to be considered in ABS contracts to ensure a fair and equitable sharing of benefits arising from the utilisation of genetic resources and aTK.
- Many countries are in the process of establishing online application systems for access to genetic resources / aTK. In some countries a full online application for access to genetic resources can be made, in other cases a user may apply online but is required to sign the application in person.
- An issue that sparked a debate among participants concerned a clause in the Ethiopian ABS regulation which determines that an access applicant who is a foreigner shall present a letter from the competent authority of his national state or that of his domicile assuring that they will uphold and enforce the access obligations of the applicant. Participants argued that it is not possible for Competent National Authorities in Europe or elsewhere to assume this role for several reasons (principle of sovereignty, human resources, etc.).
- Benefit-sharing options can differ depending on the national context. Some countries have set up national benefit-sharing funds and predetermined benefit-sharing percentages in their national laws.
- There is a need for more capacity-building, especially with regard to IP tools for the protection of traditional knowledge. A question that arose in this context was whether intellectuel property could be a sufficient tool to protect traditional knowledge. Some participants pointed out that there is little awareness and understanding of the various intellectual property instruments that exist to protect traditional knowledge associated with genetic resources.

- The discussions also drew attention to the importance of populating the ABS Clearing-House, a key instrument aimed at providing transparency on procedures for access, and for monitoring the utilization of genetic resources along the value chain, including through the internationally recognized certificate of compliance (IRCC).
- Further, the visualization of ABS procedures in the form of flowcharts was considered useful by many participants. User representatives enquired whether such documents could be made available on the ABS Clearing-House.

16 Key Access Questions

In this session, moderated by Suhel al-Janabi, participants identified key access questions and „take home“ messages from this meeting. These can be summarized as follows:

- A(ccess) and B(enefit-sharing) need to be linked. Many countries have established strict access rules to prevent misappropriation of GR. Users and providers of GR/ aTK have different concerns and these need to be brought together. A key question that needs to be addressed in this regard is: How can we ensure benefit-sharing in order to facilitate access?
- Benefit-sharing should be targeted for the conservation of biodiversity. Many countries directly involve the local people, which is to be considered a good approach. If benefits are shared among the local populations this will help encourage them to conserve biodiversity.
- More trust between users and providers of GR / aTK is required to make ABS work. How can this evolve? Discussions revealed that regulations, such as the EU ABS regulation, raise awareness and encourage actors including providers to trust the system.
- There exists a diversity of access rules. How can users learn to navigate given the diversity of ABS systems at country level? It is important to identify the commonalities. Differences can be addressed particularly by guiding users. It is promising from a user perspective that countries aim for more harmonization. It is key to continue in this spirit of cooperation and head towards further collaboration. Further brainstorming may be useful to find out whether variations in approaches can be narrowed down.
- The Nagoya Protocol sets out an obligation for Parties to collaborate. The workshop was an ideal platform to implement this obligation. Further events will be organized to follow up on this collaboration obligation. This meeting has shown that a more informal setting as in Vilm can be very helpful for discussions.
- Information exchange on ABS needs to be continued. Many users wish to comply with national legislation. The central way to advance this exercise of information sharing is to upload information on the ABS Clearing-House. If users comply with ABS rules and regulations, countries will in the long run tend to make access easier for applicants, resulting in more benefits for provider countries (“win-win” situation).
- Access to GR / aTK as such is not the whole picture of ABS. It is crucial for stakeholders to understand the interplay of access and compliance. A workshop organized by the European Commission in November 2017 aims to address this issue. In the future there is also a need to explore value chains from beginning to end, allowing stakeholders to understand how compliance measures were drafted and how the

system works in practice (role of Internationally Recognized Certificates of Compliance, checkpoint communiqués, etc.).

- Behind every access law, there stands a policy objective and this policy objective may change. The objective of the national legislation frames the whole ABS set-up and is therefore fundamental. In Brazil for example, the former ABS legislation focused entirely on access with a view to avoid biopiracy. It took many years to make the ABS approach in Brazil more user friendly since it is very difficult to transform an approach which was developed under a different mindset. However, due to many users in Brazil, the difficulties were understood and the approach was changed.
- There needs to be simplified access to genetic resources for researchers. In France for example, the law restricts researchers by making it difficult for them to apply for access to GR and to obtain authorizations.
- The advantages of online systems for sharing information and permitting processes have been underlined; some countries are in the process of developing online systems.
- European CNAs need to exchange and cooperate with provider countries on cases of non-compliance.
- Peer-to-peer exchange must continue, but it is not the only means. More information needs to be published on the ABS Clearing-House. Uploading access measures on the ABS Clearing-House is important, but providing diagrams / flowcharts would also be very useful. A question that arose in this context was whether provider countries would be willing to upload this information (e.g. with a legal disclaimer) on the ABS Clearing-House.
- Participants agreed that the dialogue contributed to a better understanding of how to access GR / aTK in selected provider countries. It was an excellent opportunity to learn from other countries implementing the Nagoya Protocol and to work on concrete solutions by looking at best practices as well as challenges.

17 Mexico as COP Presidency

Ms. Edda V Fernández Luiselli, Director General for the Primary Sector and Renewable Natural Resources, Underministry for Environmental Promotion and Regulation, SEMARNAT, ABS National Focal Point;

Ms. Romana Alejandra Barrios Perez, Director for Biodiversity, Biosafety and Genetic Resources, Underministry for Environmental Promotion and Regulation, SEMARNAT

Fig. 36: Ms. Edda V Fernández Luiselli

Fig. 35: Ms. Romana Alejandra Barrios Perez

17.1 Current Process towards Access Regulations

Mexico in accordance with the recognitions of its natural and cultural capital in terms of number, species, endemism, ecosystems diversity and historic and cultural heritage, as part of the Like Minded Megadiverse Countries Group, has always been an active part of all the negotiation process which resulted in the adoption of the Nagoya Protocol in 2010, and is now promoting its implementation.

In 2014 the Mexican Senate ratified the Nagoya Protocol (NP) and the Executive officially published the Decree in October 10, 2014. In accordance with our Constitution, the compliance with the Nagoya Protocol is mandatory (Article 133). In other words, for Mexico the Nagoya Protocol dispositions are automatic-receiving to the national legal system.

Therefore, the Nagoya Protocol is legally binding in the Mexican territory and to be implemented by the Competent National Authorities (CNAs). Its implementation will be further supported by related secondary legislation.

The current Mexican legislation operative in ABS are the General Law of Ecological Equilibrium and the Protection of the Environment, the General Law of Sustainable Forest Development, the General Law of Sustainable Rural Development and the General Law of Wildlife.

Since 2014, the Ministry of Environment and Natural Resources (SEMARNAT), through the Directorate-General for the Primary Sector and Natural Renewable Resources (National Focal Point), established and coordinates an inter-ministerial working group to implement the Nagoya Protocol in Mexico. This working group is integrated by seventeen governmental agencies belonging to different sectors: Agriculture, Economy, Human Health, Seeds

Inspection, Intellectual Property Office, Indigenous Peoples Commission, Biodiversity Commission, the Environment Sector and Foreign Affairs.

The inter-ministerial group has defined that the subject matters to be regulated under the Nagoya Protocol in Mexico are the ATK, GR and their derivatives. The basic principles to be considered are:

- Alignment with the national legal framework

- Recognition of environmental and cultural values.
- Consideration of:
    - Regulation of all GR and users
    - The State as guarantor
    - Special considerations according Article 8 of NP, including change of intent
    - Beneficiaries: indigenous peoples, local communities, private holders or the Union (ABS National Fund).

As to this date, the working group has designed and adopted a specific process under an administrative approach. This process includes special regimes for commercial and non-commercial access to GR, and involves the participation of the NFP and the CNAs.

The simplified regime for noncommercial purposes has the following characteristics:

- The applications to be resolved in 30 working days by CNA
- PIC: Only for ATK or GR belongs to the IPLCs projects (formats)
- MAT: Response letter to deliver the results to the CNA and the communities as appropriate

The commercial Regime in contrast is:

- The applications to be resolved in 90 working days by CNA
- (from when PIC is granted)
- PIC:
    - IPC
    - LC
- MAT: Access Agreement
- Benefits:
    - Communities
    - National Fund (when it is difficult to define the original provider)

At this moment Mexico has two main CNAs:

- SEMARNAT: Wild Species, Forestry and Soils, Crop Wild Relatives and marine or aquatic species listed in the Endangered Mexican Species List and “other” not covered by SAGARPA

- SAGARPA: Domesticated cultivars, Livestock, zoo and phytosanitary GR and marine or aquatic GR

The National Commission for the Development of Indigenous Peoples (CDI) is the consultative body for advice on indigenous issues and to obtain the PIC.

The Ministry of Foreign Affairs is competent for GR in National Jurisdiction Waters according to UNCLOS.

At the time of the Vilm Dialogue, the NFP has received 32 users consultations regarding the process to obtain an access permit:

Tab. 13: Overview of user consultations and permits granted

User country of origin	**Consultations**	**Permits granted**
Germany	6	
Austria	1	
France	5	
UK	2	
Japan	2	1
USA	4	1
The Netherlands	2	
National users	11	
Spain	1	Almost

In parallel to those activities, the inter-ministerial group has also designed and developed a proposal for the secondary law that will further strengthen the legal and technical aspects needed for the implementation of the NP in the Mexican context.

Taking into account Art. 22 of the NP, Mexico designed and presented to GEF a project that focuses on capacity building. The project considers the particularities of Mexican social groups, including indigenous peoples (68) and local communities. The project also considers the improvement of the legal and administrative framework on ABS, while building capacities in relevant governmental agencies such as SEMARNAT, the Ministry of Economy (SE), the Mexican Institute of Industrial Property (IMPI), the Federal Attorney of Environmental Protection (PROFEPA), the National Commission for Natural Protected Areas (CONANP), the Ministry of Agriculture, Livestock, Rural development, Fishery and Food (SAGARPA), the National Commission for the Development of Indigenous Peoples (CDI), and the National Commission for Knowledge and Use of Biodiversity (CONABIO).

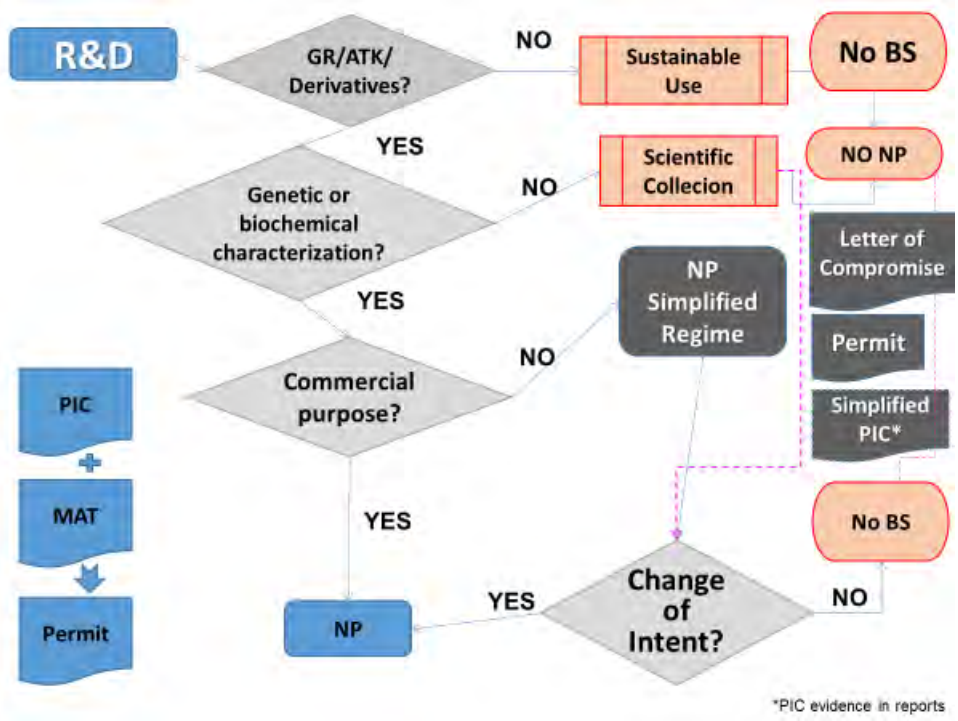

Fig. 37: Flow Chart Mexico 1

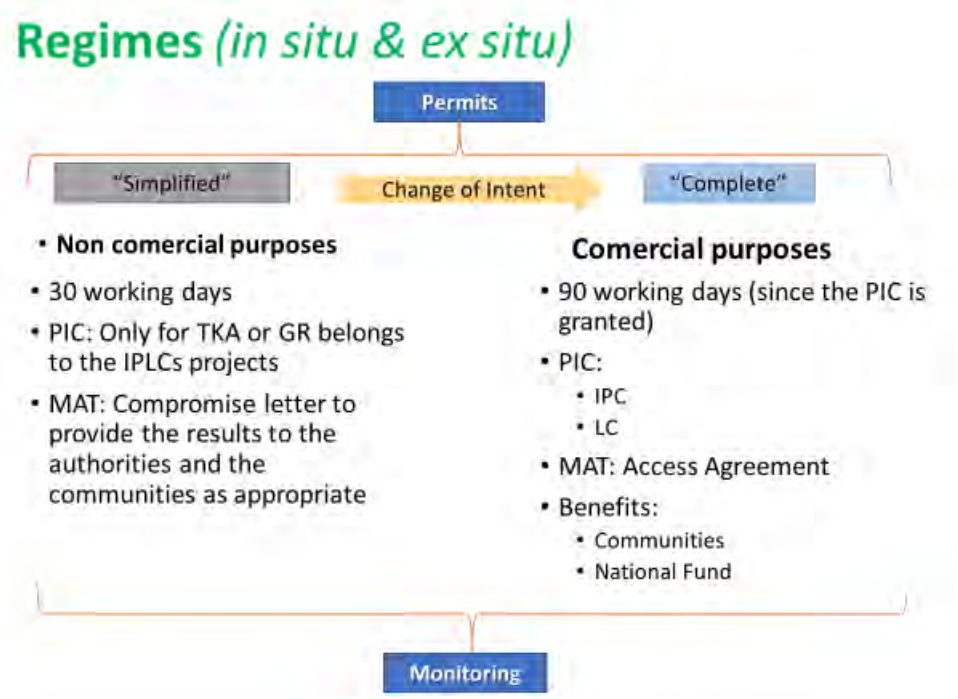

Fig. 38: Flow Chart Mexico 2

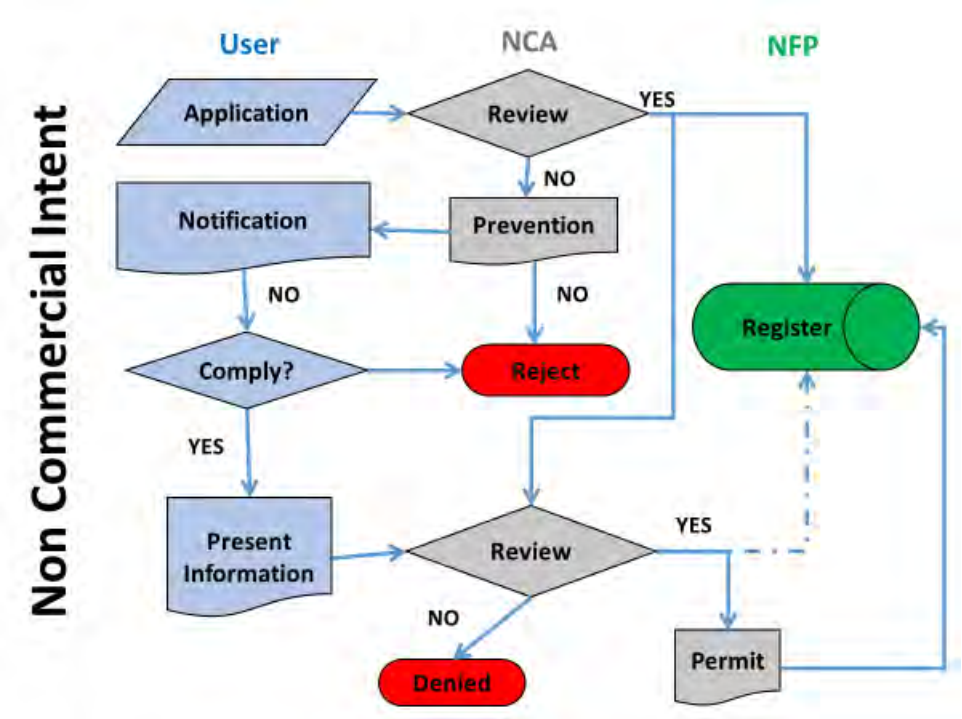

Fig. 39: Flow Chart Mexico 3

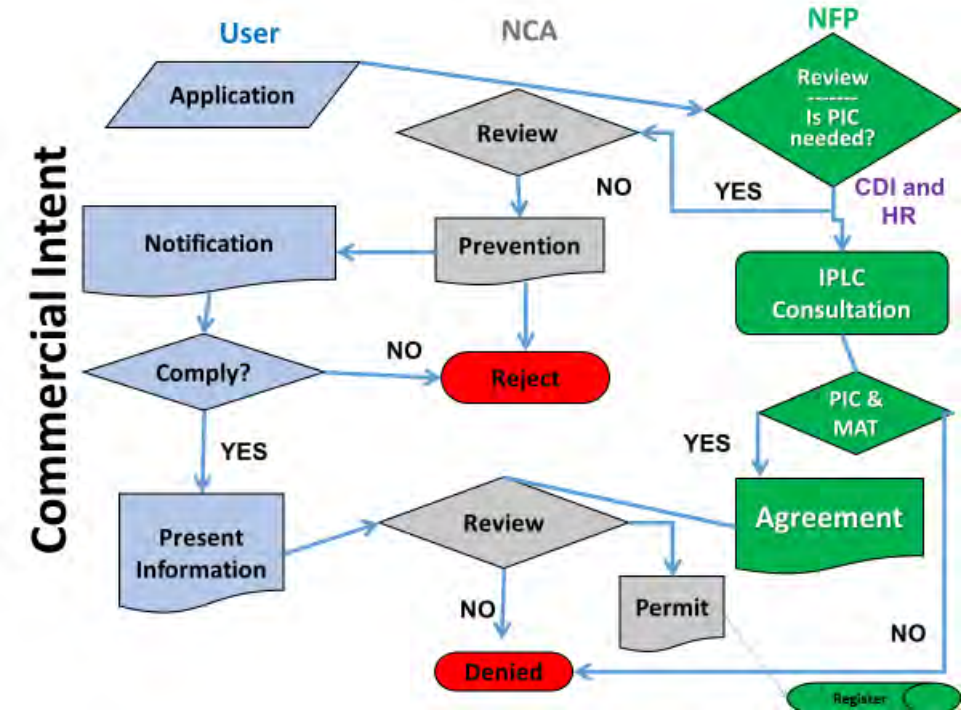

Fig. 40. Flow Chart Mexico 4

17.2 **Access Profile**

Tab. 14: Access profile Mexico

Criteria	**Acquired information**	**Comments**	**Source**
Party Nagoya Protocol	yes		ABS -CH
Signatory	yes		ABS -CH
NFP (National Focal Point)	yes	Edda Fernandez Director General for the Primary Sector and Renewable Natural Resources, SEMARNAT	ABS -CH
Contact NFP	00 52 55 56280736; 0052 55 56280600 ext 12041; edda.fernandez@semarnat.gob.mx	Additional contact: Alejandra Barrios (SEMARNAT) alejandra.barrios@semarnat.gob.mx 0052 55 56280600 ext 10661	ABS -CH Revised by the NFP
CNA (Competent National Authority)	yes	All applications must be presented at SEMARNAT (Main Offices). The consultation to the NFP may be done by mail.	ABS -CH
Contact CNA	National Service for Seed Inspection and Certification. Ministry of Agriculture, Livestock, Rural Development, Fishery and Food (SAGARPA) Guilllermo Pérez Valenzuela # 127, Colonia del Carmen Coyoacán, Ciudad de México, Deleg. Coyoacán C.P. 04100, Mexico +1 525 538711000 ext. 47000 +1 52536220667 ext. 2002 manuel.villaissa@sagarpa.gob.mx		

Criteria	Acquired information	Comments	Source
	Dirección General de Gestión Forestal y de Suelos (DGGFyS) Subsecretaría de Gestión para la Protección Ambiental Secretaría de Medio Ambiente y Recursos Naturales (SEMARNAT) Avenida Progreso No. 3, edificio 3, planta alta, Colonia del Carmen, Coyoacán, Ciudad de México, Deleg. Coyoacán C.P. 04100, Mexico 1+ 52+ (55) 54843568 1+ 52+ (55) 54843505 augusto.mirafuentes@semarnat.gob.mx		
	Dirección General de Vida Silvestre, Subsecretaría de Gestión para la Protección Ambiental, Secretaria de Medio Ambiente y Recursos Naturales (SEMARNAT) Av. Ejército Nacional 223, Col. Anáhuac. Ciudad de México, Delegación Miguel Hidalgo C.P. 11320, Mexico 1+52+(55) 54900900 ext 23306 josel.funes@semarnat.gob.mx		

Criteria	Acquired information	Comments	Source
	Comisión Nacional para el Desarrollo de los Pueblos Indígenas (CDI) Av. México-Coyoacán 343, Col. Xoco México, Benito Juárez 03330, Mexico +1 525 91832100 +1 525 56-05-43-61 dirgral@cdi.gob.mx ibet-anzos@cdi.gob.mx derechosin-digenas@cdi.gob.mx ainternacion-ales@cdi.gob.mx		
CNA Deputy	No		Revised by NFP
Contact CNA Deputy			Revised by NFP
Relevant competent authorities of IPLCs (Indigenous Peoples and Local Communities)	yes	Comisión Nacional para el Desarrollo de los Pueblos Indígenas (CDI) (National Commission for the Development of Indigenous Peoples)	Revised by NFP
ABS law	in process	In 2014 Mexico ratified the Nagoya Protocol (NP) and officially published the Decree in October 10, 2014. In accordance with our Constitution, the compliance with the Nagoya Protocol is mandatory (Article 133). In other words, for Mexico the Nagoya Protocol dispositions are automatic-receiving to the national legal system. Mexico is working on additional legislation for the national implementation process. Since 2014 SEMARNAT, through the National Focal Point for Mexico, established and coordinates an inter-ministerial working group to this end. As to this date, the working group has designed and adopted a specific process under an administrative approach. This process includes special regimes for commercial and non-commercial purposesaccess to GR, and involves the participation of the NFP and the Competent National Authorities (CNAs). The working group has also designed and developed a proposal for the secondary law that will further strengthen the legal and technical aspects needed for the implementation of the NP in the Mexican context.	Revised by NFP

Criteria	Acquired information	Comments	Source
Specific access regulation	in process	An administrative process has been designed and adopted. It includes special regimes for commercial and non-commercial purposesaccess to GR, and involves the participation of the NFP and the Competent National Authorities (CNAs). A proposal for the secondary law that will further strengthen the legal and technical aspects needed for the implementation of the NP in the Mexican context has been designed and developed.	Revised by NFP
Specific access procedures (law or any defined process) for non-commercial use	in process	An administrative process has been designed and adopted. It includes special regimes for commercial and non-commercial purposesaccess to GR, and involves the participation of the NFP and the Competent National Authorities (CNAs). A proposal for the secondary law that will further strengthen the legal and technical aspects needed for the implementation of the NP in the Mexican context has been designed and developed.	Revised by NFP
English translation for users available	No	The official language in Mexico is the Spanish. Courtesy translations might be developed in time.	Revised by NFP
Visualization of ABS procedure	Not yet	The needed information for permits requests is provided by the NFP on a case by case basis.	Revised by NFP
Information on access procedure / regulations accessible through weblink	No		Revised by NFP
Access request form	yes	In the cases of forestry GR, the actual permit format is : Scientific Collection for Biotechnology Commercial purposes (SEMARNAT-03-058-B) https://drive.google.com/file/d/0ByzIMoBRT-FBuWDVXY1oycXp6WVE/view	Revised by NFP
Specific access demand form for non-commercial purposes	yes	It is defined by the final purpose of the utilization	Revised by NFP
Online application system	No	All applications must be presented to the Central Offices of SEMARNAT. The consultation to the NFP may be done by mail.	Revised by NFP
Compulsory documents for access demand application	yes	Site of collecting, targeted species, objectives of research, etc.	Revised by NFP

Criteria	Acquired information	Comments	Source
Submission of access application at	SEMARNAT or SAGARPA		Revised by NFP
Access fees	yes	As for today, $15 USD per application for thttps://drive.google.com/file/d/0ByzIMoBRT-FBuWDVXY1oycXp6WVE/view	SEMARNAT web site
Other permits prerequisite to obtain ABS permit	yes	Any export of biological material requires to comply with phytosanitary measures. International researches require a special permit from the Ministry of Foreign Affairs to carry out research related activities in Mexico.	
IRCC (Internationally Recognised Certificate of Compliance)	yes	To date, two IRCC have been uploaded in the ABS-CH	ABS-CH
Have ABS permit(s) been issued in the country?	yes	Access permits for two cultivated species - by SNICS. According to the national legislation in force	ABS-CH
ABS permit(s) issued by	SNICS - SAGARPA		ABS-CH
Average timeline (from access demand to permit)	not defined		ABS-CH
MAT(s) signed	Yes	Please refer to the Certificates: https://absch.cbd.int/database/IRCC/ABSCH-IRCC-MX-208823/1 and https://absch.cbd.int/database/IRCC/ABSCH-IRCC-MX-207343/3	Revised by NFP
MAT(s) to be signed with	Providers	GR Providers in both cases	Revised by NFP
Standard MAT clauses	no	Case by case	Revised by NFP
PIC(s) granted	yes	At two levels: by the provider (when clearlly identified) of the genetic resource and by the authority which grants the permit	Revised by NFP
PIC(s) to be granted by	SEMARNAT, SNICS, (pursuant with the issued permits)	And also by the GR/ATK providers	Revised by NFP

17.3 Options for Integrating the Dialogue Results into the Intersessional Period Until MOP3 under Mexican COP/MOP Presidency

The final presentation, held by Ms Edda Fernández, ABS National Focal Point and Director General for the Primary Sector and Renewable Natural Resources at the Underministry for Environmental Promotion and Regulation, SEMARNAT (Mexico) addressed options for integrating the dialogue results into the intersessional period until the Meeting of Parties (MOP) 3 under the Mexican COP / MOP presidency.

Ms Fernandez highlighted that the dialogue has provided very useful information on national ABS procedures and has shown the importance of dialogue between competent national authorities. She indicated that the report of this meeting should be made available at SBI-2 as information document. Further understanding and exchange may be useful on the monitoring system established under the ABS Clearing-House and how it can contribute to benefit sharing.

In her presentation, Ms Fernandez pointed to the importance of experience exchange in workshops. It is key to gather a common understanding on (1) similarities and differences of ABS frameworks and procedures and (2) how monitoring the utilization of genetic resources through the ABS Clearing-House and sharing of experiences would be useful to support benefit-sharing under the Nagoya Protocol. Ms Fernandez also pointed to the need for a better understanding of the system already established and how to use it.

As to next steps, Mexico is considering to host an ABS dialogue in 2018 focusing in particular on associated traditional knowledge, benefit sharing, digital sequence information and possibly Art. 10 with a view to further support the implementation of the Nagoya Protocol.

A one-day workshop over the weekend of SBI 2-SBSTTA 22, taking place in July 2018 in Montreal, may be another opportunity for monitoring and experience exchange between countries.

18 Way forward and Closure

Before the ABS Dialogue was brought to a close, participants were invited to share their ideas concerning future cooperation forms for an effective implementation of the Nagoya Protocol.

These included:

- the exchange of ideas between ABS National Focal Points / Competent National Authorities through a closed blog based on the ABS Clearing-House,
- annual face-to-face dialogues,
- webinars to exchange “hot topics”, emerging issues and ABS cases,
- regular teleconferences with specific agendas to exchange on specific topics,
- identifying case studies that will be taken through the access requirements of a provider country and the compliance measures of a user country and sharing the preliminary findings during a future ABS Dialogue,
- sharing information on patents found by officials of Commissions of Biopiracy with CNAs in the user countries (case of Peru).

Valerie Normand (SCBD) thanked everyone for their active engagement in discussions and encouraged participants to make relevant information available on the ABS Clearing-House.

She also made reference to the meeting of the Subsidiary Body on Implementation (SBI) in July 2018 which aims at considering the assessment and review of effectiveness of the Nagoya Protocol.

Ute Feit (BfN) thanked all participants for sharing their experiences and the facilitators of GeoMedia for organizing this event. She highlighted that the ABS Dialogue 2017 has allowed the champions of ABS implementation to discuss their experiences with setting up and running an ABS system. Lessons learnt will be made available to countries that are in the process of translating the Nagoya Protocol into domestic legislation through an Informative Document and/or a side event at SBI and / or COP 14 / MOP 3. Mrs Feit further informed participants about the second ABS Dialogue on the Isle of Vilm which will be held by the Federal Agency for Nature Conservation in cooperation with GeoMedia GmbH in September 2018.

Overall, the active involvement of the participants and the interactive format of the dialogue 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

List of Participants

Agenda

ABS Scenario Discussion

- India
- Brazil
- Peru
- Costa Rica

Country Presentations

- Viet Nam
- Ethiopia
- India
- Brazil
- Peru
- Kenya
- Costa Rica
- Philippines
- South Africa
- Australia
- Mexico