

GUIDELINES

On Access to Biological Resources & the Fair and Equitable Sharing of Benefits Arising from their use

January 2019

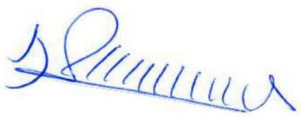
FOREWORD

Malawi has a number of species of plants, animals, and microorganisms that provide multiple benefits in terms of goods and services. The enormous diversity of genes in these species coupled with traditional knowledge on the use of the resources by communities; also provides genetic variants and valuable information for research and development in a number of sectors including crop development, food technology, cosmetics and pharmaceuticals. There is need for proper procedures for the fair and equitable sharing of the benefits realised from the use of the biological resources and their associated traditional knowledge.

These guidelines have been developed to lay out conditions under which access to biological resources in Malawi will be granted and the fair and equitable sharing of benefits arising from the utilisation of biological resources shall be ensured. The guidelines also provide for the institutional frameworks within which the access and benefit sharing shall operate.

The guidelines shall apply to the access and utilisation of all biological resources and traditional knowledge associated with the use of biological resources for research, development and bio-trade. Users of the guidelines may include, but not limited to; academics, students, public and private institutions, public and private breeding companies, commercial entities, multinational companies, bio-traders, biological resources collectors, protected area staff, researchers, civil society and concerned local communities.

These guidelines have been developed in accordance with the Environment Management Act and other sectoral legislation such as the Forestry Act, Fisheries Conservation and Management Act National Parks and Wildlife Act, Control of Animal Diseases Act, Science and Technology Act and Plant Protection Act. The development of these guidelines also reaffirms Malawi's commitment to the achievement of the objectives of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation.



Patrick .C. Matanda

Secretary for Natural Resources, Energy and Mining

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ACRONYMS

ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
CAN	Competent National Authority
DNA	Designated National Authority
DNPW	Department of Parks and Wildlife
EMA	Environment Management Act
IPR	Intellectual Property Rights
LUANAR	Lilongwe University of Agriculture and Natural Resources
MAT	Mutually Agreed Terms (Also referred to as ABS contract)
NBSAP	National Biodiversity Strategy and Action Plan
PIC	Prior Informed Consent
TK	Traditional Knowledge
UNDP	United Nations Development Programme

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Authors :

Environmental Affairs Department

Private Bag 394

Lilongwe 3

Malawi

Phone: +265 (0) 1 771 111

www.ead.gov.mw

Cover Photos:

Picture of Fungi on Mt Mulanje courtesy of Mphatso Kalemba

Insects on back cover courtesy of Raymond Murphy



Palpopleura lucia, female

Photo Credit: WESM

1. Introduction



Pseudagrion sublacteum, male

Photo Credit: WESM

Malawi is endowed with diverse biological resources which contribute significantly to the country's economy both directly as source of livelihood for the majority of the population and indirectly through various ecosystem services. Recently there has been growing demand for these resources for research and/or development and bio-trade, both from local and foreign users. This growing demand for biological resources has also been accompanied by the demand for traditional knowledge associated with the use of these biological resources. Economic interests linked to these resources have prompted an interest on the importance of securing property rights and regulating access.

The rising demand for biological resources has created challenges in ensuring sustainable utilisation and conservation of these resources. These challenges include illegal access of biological resources, unequal sharing of benefits arising from use, loss of export revenue and unsustainable harvesting of resources. These challenges emanate from lack of ABS procedures, lack of institutional coordination with regard to access and export of biological resources including conflicting mandates amongst institutions; limited institutional knowledge and capacity on ABS and inadequate systems for monitoring compliance to ABS legislation. As a result, communities and institutions that own genetic resources and associated traditional knowledge have not substantially benefited from their utilization.

These guidelines have therefore been developed to address some of the outlined challenges and lay out conditions under which access to biological resources in Malawi will be granted and the fair and equitable sharing of benefits arising from the utilisation of biological resources shall be ensured. Furthermore, the guidelines provide for the institutional frameworks within which the guidelines shall operate.

1.1 Legal Context

Malawi has been regulating access to, and benefit sharing of biological resources in accordance with the Environment Management Act (Cap. 60:02 of the Laws of Malawi) as well as sectoral legislation including the Forestry Act
(Cap. 63:01 of the Laws of Malawi) Fisheries Conservation and Management Act (Cap. 66:05 of the Laws of Malawi), National Parks and Wildlife Act (Cap. 66:07 of the Laws of Malawi), Control of Animal Diseases Act (Cap. 66:02 of the Laws of Malawi), Science and Technology Act (Cap. 37:01 of the Laws of Malawi),) and Plant Protection Act (Cap. 64:01 of the Laws of Malawi), The EMA empowers the Minister to facilitate development of national strategies, plans and programmes for the conservation of biological diversity as well as ensuring access, and fair and equitable benefit sharing.[1]

These guidelines will support the objective of the National Biodiversity Strategy and Action Plan (NBSAP) which is to contribute to management of biodiversity for economic growth and wellbeing of present and future generation

At international level, Malawi is a party to the United Nations Convention on Biological Diversity (CBD). The convention has three main objectives: the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilization of genetic resources. One of the protocols under the CBD is the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from utilisation. Malawi ratified the protocol in 2014 to ensure that benefits from resources are shared in a fair and equitable manner. The development of these guidelines has therefore been guided by both international and national legislation.

1.2 Objectives of the Guidelines

The main objective of these guidelines is to define procedures on access to and ensure the fair and equitable sharing of benefits arising from the use of biological resources. Specifically, the guidelines seek to:

a) Provide procedures required to obtain permits for access, import and export of biological resources, information and Traditional knowledge associated with the use of biological resources;

b) Provide roles and responsibilities of Designated National Authority (DNA) Competent National Authorities' (CNA's) and relevant stakeholders;

c) Provide guidance on mechanisms for fair and equitable benefit sharing.

d) Provide details of rights and obligations of users and providers;

e) Promote awareness to stakeholders on basic principles and concepts of ABS, with a special view regarding the relationship between the permits and the ABS Contracts;

1.3 Scope of the Guidelines

The guidelines shall apply to the access and utilisation of all biological resources, information and traditional knowledge associated with the use of biological resources for research, development and bio-trade. The guidelines shall also provide procedures for the fair and equitable sharing of benefits realised from the use of biological resources. Users of these guidelines may include, but are not limited to; academics, students, public and private institutions, public and private breeding companies, gene banks holding collections of biological resources, databases holding information in any form on biological resources, commercial entities, multinational companies, bio-traders, biological resources collectors, protected area staff and managers, researchers, civil society and communities.

Providers of biological resources and traditional knowledge are communities, individuals, institutions, land owners and organs of the state within the following categories:

a)Those who provide access to the biological resource and/or information on biological resources

b)Those who provide information on traditional use and or knowledge associated with biological resources

1.4 Guiding Principles

These Guidelines shall operate under the following principles:

a) As custodians and users of biological resources, local communities have knowledge, skills and information which can be utilized to promote access to and the fair and equitable sharing of benefits arising out of utilization of biological resources; Benefit sharing is therefore an incentive for conservation and sustainable use of biological resources by communities.

b) Coordination among various stakeholders at all levels is essential to ensure access to and fair and equitable sharing of benefits arising from utilisation of biological resources;

c) Harmonisation with International, regional and national cooperation on access to and fair and equitable sharing of benefits arising from utilisation of biological resources, including sharing of information and appropriate technology, is crucial;

d) The Government is responsible for providing direction and leadership in ensuring access to and fair and equitable sharing of bene fits arising from utilisation of biological resources;

e) Community engagement and participation in decision making in granting access to and fair and equitable sharing of benefits arising from utilisation of biological resources requires that individuals and policy makers have a better understanding and appreciation of biodiversity.

f) Collection and/or harvest of biological resources shall be conducted in a manner that does not exceed the sustainable yield of biological resources of an ecosystem and that does not impair ecosystem structure, functions, and services.



Photo Credit: WESM

Calidea dregii

2. Conditions for an ABS Contract and Permits



Community Outreach

2.0 Conditions for an ABS Contract and Permits.

An ABS contract and permits shall be provided in order to ensure access to and fair and equitable sharing of benefits triggered by the following pre-conditions:

a)If the activities being conducted by the user do not involve collection of biological resources and/or use of traditional knowledge and/or use of genetic information or any forms of DNA/ RNA sequences or sequence data in any format associated with a biological resource, no ABS contract is necessary. However, other permits may be required

b)If the activities being conducted by the user involve the collection and export of biological resources, use of traditional knowledge and/or use of genetic information or any forms of DNA/ RNA sequences or sequence data in any format associated with a biological resource, an access and/or export permits will be required;

c) An ABS Contract becomes mandatory when the user applies for an export permit for utilisation of biological resources and/or their associated traditional knowledge and or other forms of in formation, including analysis and study abroad and /or research involving various steps, including possible research for commercial purposes,

d) bio-trade or the use of traditional knowledge. Some of the specific conditions for ABS include:

i. Research and/or development of the biological resource including the genetic material, any bioactive compounds produced by or identified from them, or any enzymes or any other active compounds and use of the results;

ii. Use of genetic information or any forms of DNA/RNA sequences or sequence data in any format, including in microbiological, digital or synthetic or in any other format;

iii. access, use and/or transfer of traditional knowledge associated with biological resources;

iv. production or development processes whose outcome is knowledge, genetic properties or traits, knowledge about any uses of them, any technology or invention based on or developed from their use, any related technology or protocol related to any biological resources, bio logical production system, breeding system, and many more.



Photo Credit: EAD

Community Outreach

3. Accessing & Exporting Biological Resources



Photo Credit: WESM

Hippo at Liwonde National Park

3.1 Accessing Biological Resources

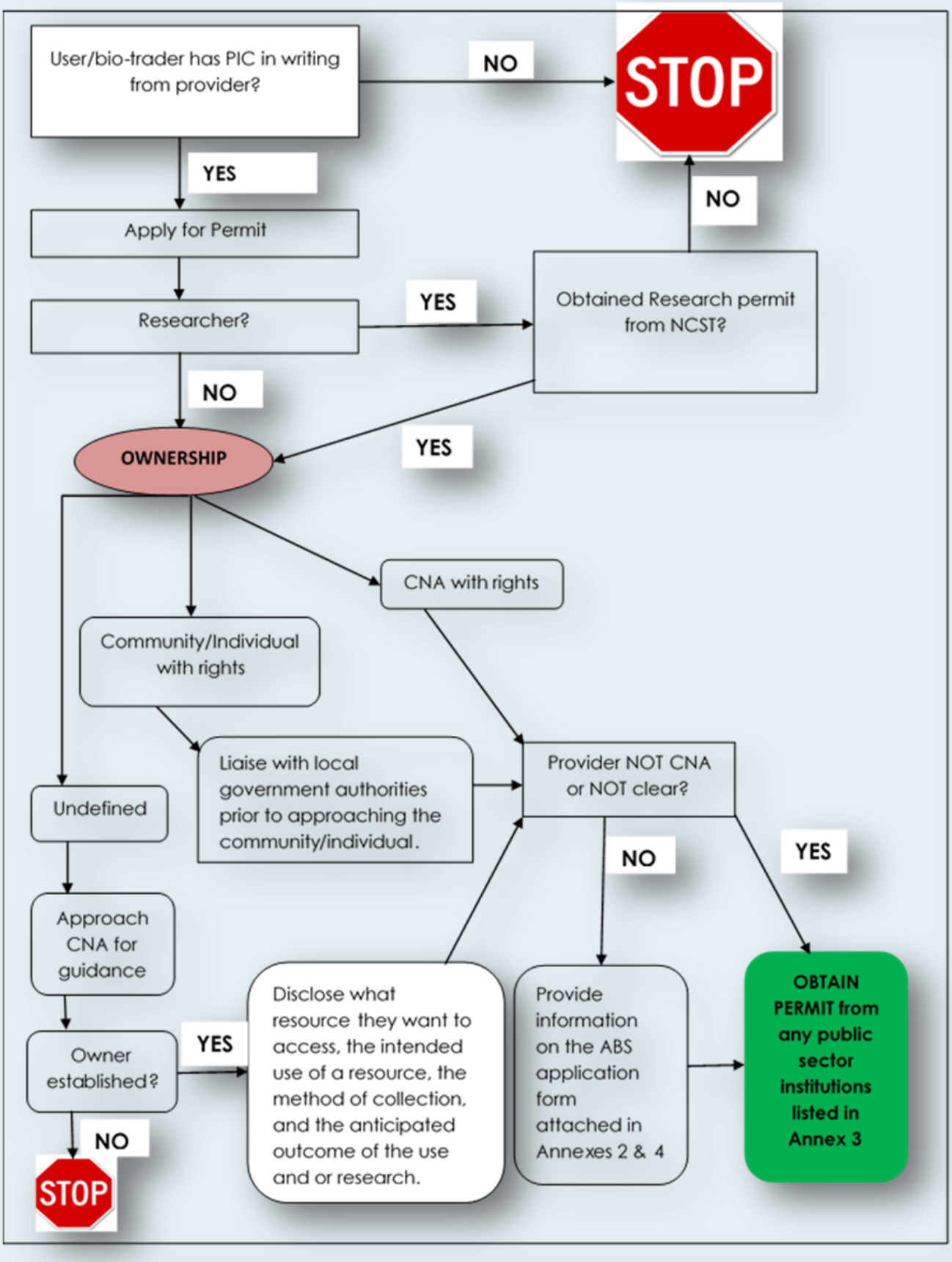


Figure 1: Flow Chart showing the process for accessing biological resources

a) Users and/ or bio-traders shall obtain Prior Informed Consent (PIC) from a provider before applying for any permit for accessing or exporting biological resources and/or their associated Traditional Knowledge and/or use of genetic information or any forms of DNA/RNA sequences or sequence data in any format;

b) The provider shall make an assessment of the nature of the resource being sought, its conservation status, ownership issues, its value and potential value before consenting to the access as guided by Annex 1;

c) PIC shall be provided in writing and submitted to the Designated National Authority and CNA as evidence of consent from the Provider by the User;

d) For researchers to get an access permit, they must obtain a research permit from the National Commission for Science and Technology after providing relevant information on their research in accordance with Annex 5;

e) Users and/ or bio-traders shall obtain an access permit from a relevant CNA/ community with ownership rights to the biological resources in question;

f) If the owner of the biological resource is a local community or an individual the User shall liaise with local government authorities prior to approaching the community;

g) If ownership is unclear a User is advised to approach the DNA for guidance;

h) Once the owner has been established a User must fully disclose what resource they want to access, the intended use of a resource, the method of collection, and the anticipated outcome of the use and or research;

i) If the provider is not a CNA, or it is unclear, the information should be provided on the ABS application form provided by the DNA attached in Annexes 2;

J) The User shall obtain access permits from any of the public sector institutions (Annex 3).



Local Acacia

3.2. Exporting Biological Resources

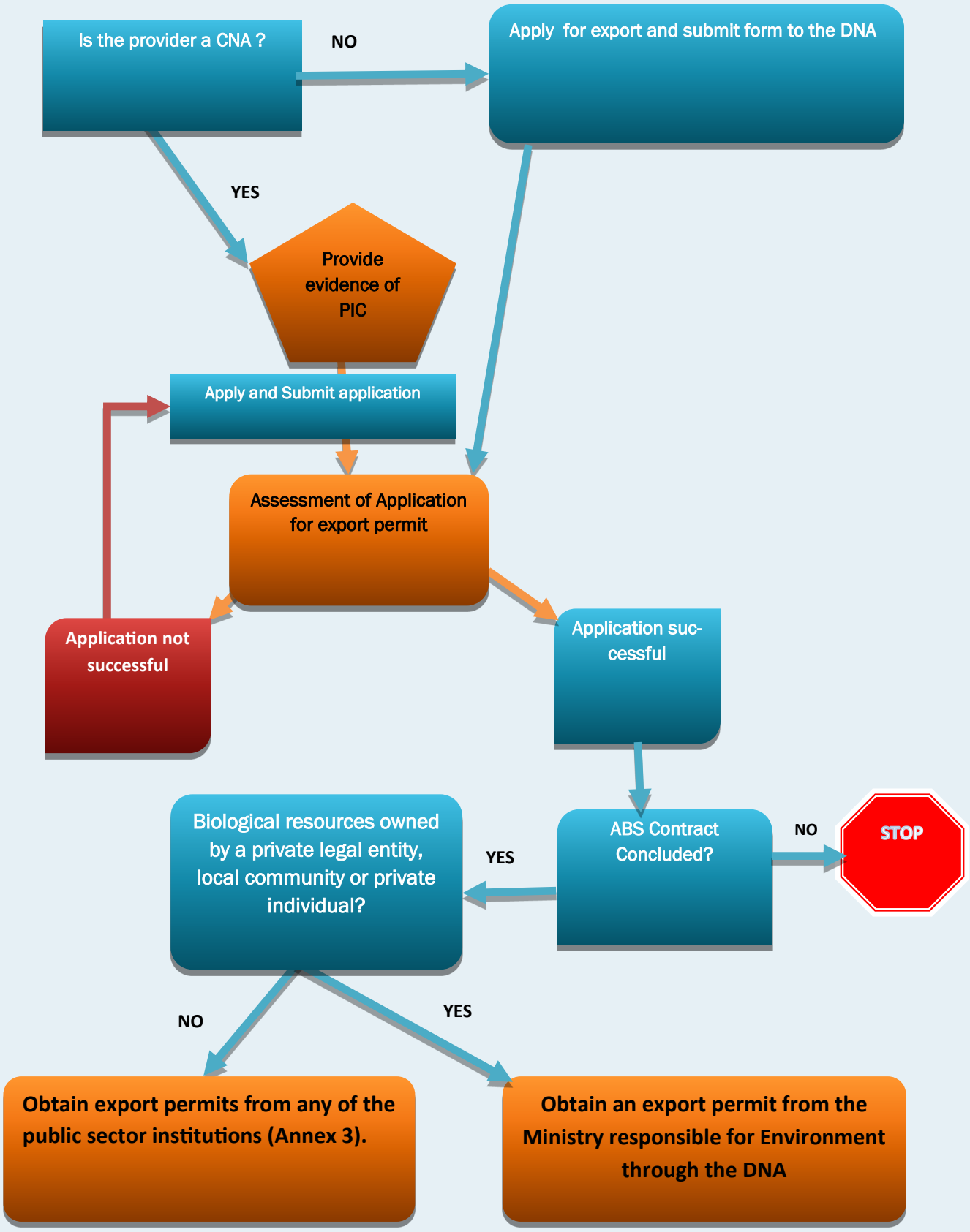


Figure 2: Exporting biological resources

In order to obtain an export permit, a user must submit an application form for export to the CNA providing the resource or the DNA if the provider is not a CNA or it is unclear .

For purposes of processing export permit of biological resources, the CNA shall use the access permit issued by the provider as evidence of PIC.

The provider and/or relevant CNA in liaison with the DNA shall assess the application and then may commence the negotiation of an ABS contract where applicable.

Upon successful conclusion of an ABS contract, users and/ or bio-traders shall obtain an export permit from a CNA.

In case of exporting biological resources owned by a private legal entity, local community or an individual, the User shall obtain an export permit from the Ministry responsible for the environment through the CNA.

The user shall obtain export permits from any of the public sector institutions (Annex 3). Figure 2 present this same procedure in a chart form.

3.3 ABS contract negotiation processes

3.3.1 Procedures prior to ABS Contract negotiation when the provider of the Biological Resource is a public sector institution.

a) The user shall make a separate application for either access and/or export to a relevant CNA who is the Provider of the biological resource;

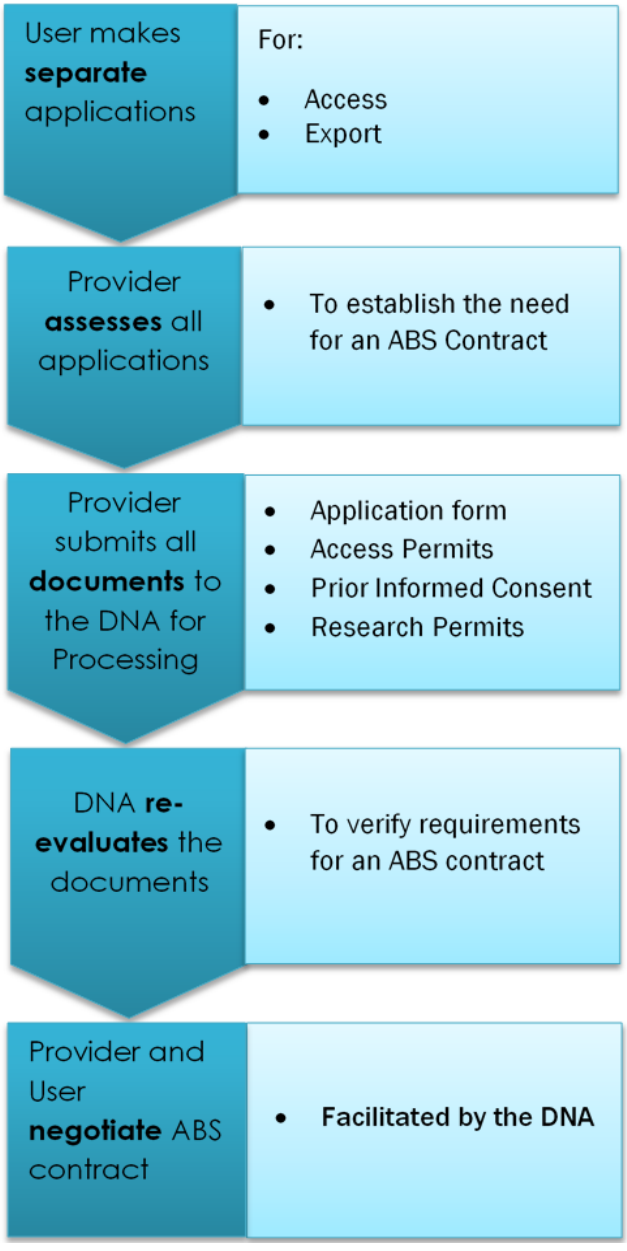
b) The Provider shall assess the application to establish the need for an ABS contract.;

c) When the need for an ABS contract is established, the Provider shall submit all relevant documents (Application Form, Access Permits, Prior Informed Consent, and/or research Permits) to the DNA for processing.;

d) The DNA shall re-evaluate the documents to verify requirements for an ABS contract;

e) When the DNA is satisfied that the user needs to enter into ABS contract, the DNA shall facilitate negotiations between the provider and the user. See Figure 3 below.

Figure 3: Negotiating an ABS Contract



3.3.2 Procedures prior to ABS Contract Negotiation when the provider of the Biological Resource is a private individual, company, local community or entity

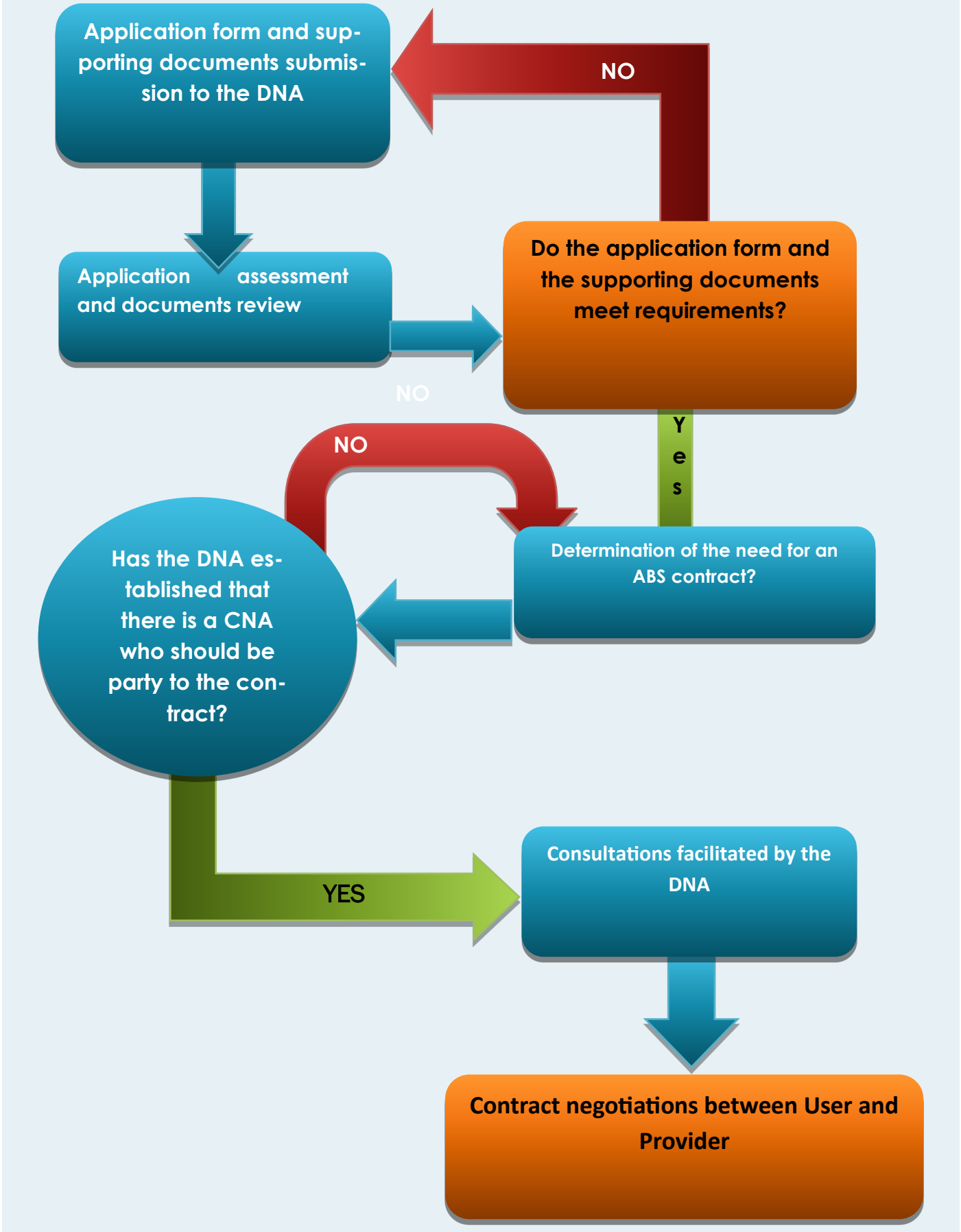


Figure 4 shows a diagrammatic presentation of procedures followed in ABS contracts where the provider is not a government institution.

3.3.3 Steps in negotiating an ABS contract for providers who are private individuals or organisations:

1. The user who seeks to apply for an export permit for biological resources obtained from private individuals, community or any other private entity shall submit an application with supporting documents (PIC, Permits, etc) to the DNA for processing.
2. The DNA shall assess the application and review the documents (PIC, access and research permits obtained by the user).
3. The DNA shall determine the need for an ABS contract.
4. Where the DNA establishes that there is a CNA who should be party to the contract, the DNA shall facilitate consultation.
5. Once the need for an ABS contract is established, the DNA shall facilitate negotiations

3.3.4 Procedures prior to ABS Contract Negotiation for biological resources exported under special considerations

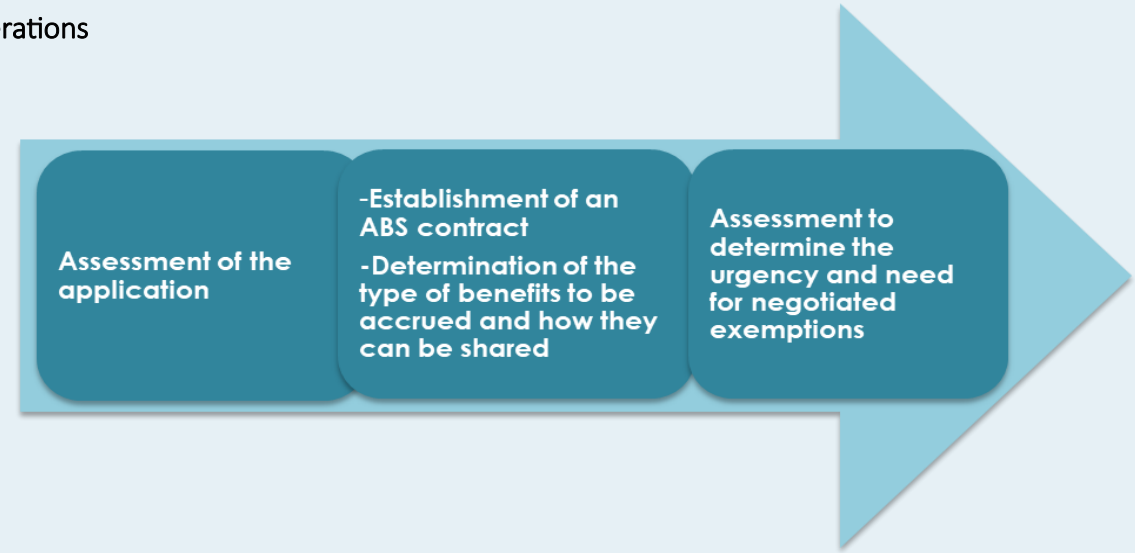


Figure 5: Steps Taken Prior to ABS Contract Negotiations

Where there are conditions requiring accessing biological resources for special uses including emergencies that threaten or damage human, animal or plant health the following procedure shall be undertaken;

a) The DNA shall expedite assessment of an application for export and determine the urgency of the use applied for

b) The DNA in liaison with the relevant CAN shall facilitate access of the biological resource and/or associated traditional knowledge and expedite the establishment of an ABS contract between the Provider and the User and determine the type of benefits to be accrued and how they can be shared.

c) The DNA shall expedite the assessment to determine the urgency and need for negotiated exemptions based on the importance of the resource and expedite export.

3.3.5 Possible benefits for negotiation

There are many benefits that shall be negotiated for depending on the type of use, the type of user, the nature of the biological resources, the nature of the traditional knowledge, the type of use of genetic information and other factors contained in the application. Annex 4 provides some of the possible benefits.

At negotiation stage, parties should consider what possible results could arise from the utilisation of biological resources and associated traditional knowledge. Parties should also bear in mind what kind of Intellectual Property (IP) implications may arise in the context of the ABS contract (MAT) in relation to the various stages of value creation. Parties should also consult IP experts when negotiating ABS contracts in order to receive guidance on the various IP implications in relation to Biological resources and innovation. Annex 5 outlines some various Intellectual Property (IP) implications arising from utilisation of



Malawi Cichlids -*Mbuna*

4. Roles and Responsibilities of Competent National Authorities and Other Stakeholders Involved In the ABS Process



Photo Credit: WESM

Gasteracantha sp.

4.1 The roles of various responsible authorities and individuals in the ABS procedure

Table 1 :Roles and Responsibilities of Various Stakeholders in ABS Procedures

ACTIVITY	RESPONSIBLE AUTHORITY/INDIVIDUAL/ ENTITY	ROLE/RESPONSIBILITY
Access and Collection	User	• Submits application for access permit to biological resources to relevant public sector institution or • Obtains PIC from provider before collecting the biological resource or using TK
	Provider: private individuals / companies/ organisations / local communities	• Provide Prior Informed Consent in writing • Provide access to biological resources or TK
	Competent National Authorities:	• Make available to the user all applicable national legislative, administrative or policy measures before granting an access permit • Provide PIC through issuing of access permits • Provide access to biological resources • Document the use of TK • Monitor the collection of biological resource and associated TK • Issue relevant export permits after entering ABS contract

	Designated National Authority	• Entry point for applicants needing information or not sure about the ABS procedures • Facilitate and Coordinate development of ABS contract between the User and Provider • Make information available for the user and provider of all applicable national legislative, administrative or policy measures on Access and Benefit Sharing • Liaise with checkpoints in order to monitor the collection of biological resources from private land owners, individuals and local communities • Facilitate documentation of TK related to biological resources • Process Export Permits where the Provider is a community, individual or not clear • Monitor compliance to the ABS contract and other relevant permits • Provide information to the Public for comments and knowledge • Provide information on ABS-Clearing House for production of an Internationally Recognised Certificate • Coordinate with neighbouring countries in case of trans boundary resources • Ensure sustainable access and recognition of holders of traditional knowledge in the Process
	Designated Check Points	• Collect and receive information on PIC and Access Permits including any other documents in the ABS Contract as evidence of compliance • Inspect relevant documents for access, transfer, export of biological resources and address issues of non-compliance
Export and negotiating an ABS contract	**User**	• Familiarise with the legislation of Malawi on ABS and approach relevant public sector institutions or communities for application of Access, Export and other permits on ABS • Submit an application in a prescribed form to a relevant CNA • Provide adequate information on utilisation in application

		• Declares whether TK is used to provider and or CNA • Get PIC from Provider and provide information to respective CNA when applying for export • liaises with CNA and provider in order to commence negotiations for ABS contract • Ensure compliance with Malawian Legislation
	Provider: private individuals/companies / organisations / local communities	• Provide evidence of PIC to CAN • Liaises with CNA and user in order to commence negotiations for ABS contract • Enter into ABS contract with the user and or any other interested party • Monitor in liaison with CNA/DNA regarding the collection and utilisation of biological resources and TK
	Provider: Public Sector Institution	• Liaise with CNA,DNA to vet application for export of biological resources • Provide evidence of PIC to CNA and DNA • Liaises with CNA and DNA and user in order to commence negotiations for ABS contract • Enter into ABS contract with the user and or any other interested party • Issue an export permit after all relevant conditions have been met including the requirement for an ABS contract
	Designated National Authority	Asses all applications for export of biological resources submitted by providing institutions and users Liaise with providers to vet applications for export of biological resources Liaise with local communities regarding the use of TK by users Liaise with local communities regarding the collection of biological resources Negotiate with users for an ABS contract in liaison with CNA Liaise with designated checkpoints to monitor compliance by users and providers Maintain and update accessible database on ABS to the general public

	Designated Checkpoints:	• Collect and receive information on PIC and access, export permits, ABS contracts and other documents in ABS as evidence of compliance and confirm with relevant CNA and DNA
	Ministry of Trade, Local government , customs and border control, inspectors, research officers, courier service providers and other designated officials	• Monitor cross boundary movement of biological resources • Inspect relevant documents for access, transfer and export of biological resources and address issues of non-compliance • Inspect the that the quantities, type and other aspects of the biological resources match with the information on the accompanying documents •
	Ministry of Justice Affairs	• Vet the ABS contracts
	NCST	• Vet application forms for research • Review reports from CNA's on research involving Biological resources

REFERENCES

Aguirre B.V. ***Documenting Traditional Knowledge-A Toolkit.*** Geneva: World Intellectual Property Organisation (WIPO, 2018).

Ahren *et al* ***An Explanatory guide to the Nagoya Protocol on access and Benefit Sharing***; (IUCN, 2012).

AU Guidelines for the Coordinated Implementation of the Nagoya Protocol in Africa (AFRICAN UNION 2015).

Ruiz M *et al* ***BioTrade and Benefit Sharing: From Concept to Practice Handbook For Biotrade and Access and Benefit Sharing Policymakers and Regulators***. (UNCTAD/United Nations Publications, 2017)

Vivas Eugui D and Adachi K (2016). Presentation at UNCTAD's workshop on ***"Addressing the intersection between the Nagoya Protocol, ABS and BioTrade"***, Hanoi, Viet Nam, June 2016. Available at ttp://unctad.org/en/pages/MeetingDetails.aspx?meetingid=1156 (accessed 30 July 2018.

GLOSSARY

Biodiversity: Refers to the variability that exists among living organisms from all sources including among other things, terrestrial, marine and other aquatic ecosystems and the ecological complexes which they are part of. This includes diversity within species, between species and their ecosystems.

Biological resources: Includes organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

Biological Material: Natural compatible biomaterials that comprise a whole or a part of a living structure including any material containing genetic information capable of reproducing itself or being reproduced in biological system.

Bio prospecting: A search for useful organic compounds in biological materials (microorganisms, animals, plants and fungi)

Bio trade: refers to those activities of collection, production, transformation, and commercialization of goods and services derived from biodiversity under the criteria of environmental, social and economic sustainability.

Genetic material: means any material of plant, animal, microbial or other origin containing functional units of heredity.

Genetic Information: the genetic potential of an organism carried in the base sequence of its DNA or mRNA according to the genetic code.

In situ and ex situ: Biological resources can be wild, domesticated or cultivated. "In situ" biological resources are those found within ecosystems and natural habitats. "Ex situ" biological resources are those found outside their normal ecosystem or habitat, such as in botanical gardens or seed banks, or in commercial or university collections.

CNA: Competent National Authority

Convention on Biological Diversity (CBD): Is an International Treaty which entered into force in 1993 which has three core objectives: the conservation of biological diversity; the sustainable use of the components of biological diversity; and the fair and equitable sharing of the benefits arising out of the utilization of biological resources.

Prior informed consent (PIC): is the permission given by the competent national authority of a provider country to a user prior to accessing biological resources, in line with an appropriate national legal and institutional framework

Mutually agreed terms (MAT): is an agreement reached between the providers of biological resources and users on the conditions of access and use of the resources, and the benefits to be shared between both parties. This can also be called an ABS Contract.

Providers: refers to institutions, communities, individuals or any person with the right to provide access to a biological resource through ownership of the resource itself or ownership or control over the land on which it grows or is found.

Users: those who seek access to biological resources for a wide range of purposes, from basic research to the development of new products. They are a diverse group, including botanical gardens, pharmaceutical, agriculture and cosmetic industries, collectors and individual researchers and research institutes and bio traders.

Designated National Authority (DNA): National focal point and entry point for ABS applications. Responsible for facilitating and providing information on ABS.

Competent National Authorities (CNAs): are bodies established by governments and are responsible for granting access to users of their biological resources, and representing providers on a local or national level.

Annex 1: Factors for communities to Consider before Granting Access to a Resource Communities may consider the following before granting access to a User to their biological resources:

1. Identify a legal representative to guide the committee that handles the process on behalf of the community.
2. The community should be fully informed about the intended use of the biological resource and/or traditional knowledge by the User prior to providing their consent.
3. The community should agree to collectively share the benefits arising from the use of the resources and develop a benefit sharing mechanism.
4. The community has the right to grant or deny access to the biological resources and/ or traditional knowledge.
5. The community should consider the status of the biological resource (conservation status etc) to ensure sustainable harvesting and use.

Annex 2: GOVERNMENT OF MALAŴI APPLICATION FORM FOR ACCESS TO AND UTILIZATION OF BIOLOGICAL RESOURCES AND/OR ASSOCIATED TRADITIONAL KNOWLEDGE FOR EXPORT

In terms of Section 36 of the Environment Management Act No. 23 of 1996

(For Official Use only)
Sector responsible for granting access.
_____

Please refer to the notes on section 2.0 on Conditions for an ABS contract and Permits before filling in the form. Complete this application form in block letters and return it duly signed with the applicable fee. Where space is insufficient for any item, attach additional signed sheets to the application form.

Type of Biological resource (Please Specify) _____

SECTION 1

1.0 Objective of the Application

This application is for (Please tick boxes that are applicable)

1.1. **Biological resource from Malawi for:**

Export ☐
Trade ☐
NON-COMMERCIAL Research ☐
COMMERCIAL or POTENTIALLY COMMERCIAL Research ☐
Other use, please specify:

_____

1.2. **Use of the genetic resource or genetic information** (Please specify components of the biological resource used in the development of products or processes. Please also specify genetic information, i.e. DNA, RNA, and Protein, Sequence data in the products or processes.)

_____

_____

_____

1.3. **In your identification of the biological resource, did you use or get a lead from any of the following:**

i. Published traditional knowledge associated with the biological material ☐

ii. Directly from a local community or traditional knowledge holders, please specify ☐

iii. Directly from one or more individual(s), please specify ☐
_____

iv. Directly from an institutions (s), please specify ☐
_____

v. From a publication please specify ☐
_____

vi. Any other sources, please specify ☐
_____

1.4. **Please specify what kind of inventions, research results of information can be expected from the biological resource including**

Knowledge about the biological resource and/or genetic properties or traits

_____

_____

Technology, invention or protocols based on or developed from the use of the biological resource

_____

_____

Knowledge developed from research or any study concerning the biological or genetic resource

_____

_____

Please Note:

i. *Clicking any of the above boxes obliges the User to negotiate and conclude an ABS Contract with the Provider or the Provider represented by the CNA as a condition to be granted permits listed in Section 5 of this application form.*

ii. *Provision of any wrongful information is a criminal offence under Section 63 of the Environmental Management Act of 1996 and relevant national and international legislation.*

SECTION 2

2.0 Information about applicant

2.1. What is the Status of the applicant (please Tick the one that applies):

☐ Juristic Person or Natural Person

☐ Organization:

a University or public research institution

i Are there any private donors to the institution in general and for this project in particular? Give information of the donors.

_____

_____

ii What is the total cost of the project? (US$_____)

b Private research institution

c Gene bank/Collection

d Student (Please specify level of studies) _____

e Private company

i. Please provide information on corporation category in which it is registered

_____

_____

ii. If a limited company, what is the capital? (US$_____)

iii When was the company registered? (dd/mm/yyyy)

f. Other (Please specify) _____

_____

2.2. Full details of applicant

Name	
Company registration number	
Identity or Passport number (if applicant is a Natural Person) (Attach a copy)	
Date of birth (if applicant is a Natural Person)	[dd/mm/yyyy]
Physical address of head office of applicant/licensee	
Postal address	

Telephone		Fax	
E-mail			

2.5. Name of the Person authorized by the legal person to act on behalf of the company *(Please provide an authenticated copy of the authorization documents)*

Designation /Title			
Institution			
Telephone		Fax	
E-mail			

Postal Address:	Physical Address:

2.7. NAMES AND CONTACT DETAILS OF INDIVIDUALS who will be involved in the activities for which access authorization is requested:

Name:	
Identity or Passport No: (Attach a certified copy)	
Tel No:	
Fax No:	
E-mail:	

Postal Address:	Physical Address:

Name:	
Identity or Passport No: (Attach a certified copy)	
Tel No:	
Fax No:	
E-mail:	
Postal Address:	Physical Address:

2.8 Details of the relevant qualifications and experience of INDIVIDUALS WHO will be involved in the activities for which access authorization is requested

Person	Relevant Qualifications or Experience

2.9. (a) Is this the first access to Malawian biological resources?

☐YES ☐NO

(b) Do you have any previous permits or contracts? ☐YES ☐NO

If yes, please specify date of application, title of application, permit number, and expiry date (if a permit was issued) and attach the permits and contracts to this application

2.10. Do you have foreign partners[2] involved?

☐YES ☐NO

2.11. If yes to 2.10 above, please provide details of foreign partners involved			
Name of foreign partners			
Contact Person			
Designation/Title			
Institution			
Telephone		Fax	

[2] Partners institutions or persons which collaborate in the project or support the project financially/in kind, such as funding agencies, foundations etc.

E-mail	
Postal Address:	Physical Address:

2.12. Where a Foreign applicant is working with a Malawian partner			
Name of Malawian partner			
Designation/Title			
Institution			
Telephone		Fax	
E-mail			
Postal Address:	Physical Address:		

2.13 What is the Physical address/location of the premises where the biological resources and traditional knowledge will be utilized (Where will the research and /or development take Place, in which countries?)

_____

_____

SECTION 3

3.0 Information about the Biological resource and/or Traditional Knowledge and or information associated with the biological resources

3.1 Provide details of the biological resources and/or Traditional Knowledge and or information in any form on the biological resource to which you are seeking access for utilization, including the quantity of biological resources and/or specific traditional to be accessed and a collection schedule. If unknown, please provide a description of collection methods and the quantity and type of organisms likely to be collected.

Common Name of the Biological Resource	Taxon (to the most specific taxonomic level known)	Amount/number/volume, including schedule (if possible)	Method of collection

Identify any listed species will be affected by the proposed action

Listed species	Amount/number/volume proposed to be sampled

3.2 How sustainable are the methods of collection?

_____

_____

3.3 Please give reasons for the amount/number/volume collected.

_____

_____

_____

_____

3.4 What is the Conservation Status of the biological resource (endemic, threatened, vulnerable or near extinct)**. Provide evidence.**

_____

_____

_____

3.5 Location: Where are the biological resources being collected? Are the biological resources trans-boundary (shared between Malawi and its neighboring countries) Physical address/location of the area where the biological resources and traditional knowledge will be accessed including the latitude and latitude or GIS coordinates of the location area (*please also attach a location map or proposed route of voyages on a separate sheet to your application*):

Location(s): _____

_____

Latitude _____ Longitude _____

_

(Please attach a map)

3.6 What are the potential impacts of the collection of the resource on the ecosystem and biodiversity in general?

_____

_____

_____

3.7 Who is going to collect the biological resource and which local institutions or communities will be involved in the collection?

_____

_____

_____

3.8 **Do you intend to re-collect at this location?** YES ☐ NO ☐

If so, when and how often?

_____

_____

3.9 How is the access to be undertaken?

Vessel/Vehicles
Equipment

3.10 If access is requested for utilization of traditional knowledge or any information related to a biological resource, please give a description of the type of information and/or knowledge ; include source, type of information or knowledge and use intended

Written Permission of Physical Access Provider: List the name of each access provider and provide a copy of his/her written permission to access genetic resources for their utilization from each access provider[3].

Access Provider
Written Permission Attached ☐

SECTION 4

If any of these categories of information is not available, please state "not available" or "not yet known" and provide a brief explanation – further evidence may be requested. If any of the required information is confidential please indicate this AND DO NOT INCLUDE IT IN THIS APPLICATION FORM but state how and on what conditions you would be prepared to disclose it to the Competent National Authority (CNA) [4.15]. Confidential information will be handled in accordance with the applicable provisions in the Basic ABS Agreement.

4.0. Information about Project, Research and/or Development

Please provide details of the Trade, Project, Research and /or Development for which the biological resources and traditional knowledge will be utilized:

4.1. Name of the Project, Research and/ or Development

_____

_____

4.1. Overall objectives of the Project, Research and/or Development (*e.g. context of the project, Research and/ or Development and possible end products*)

_____

[3] Subject to national legislation or regulatory requirements, also an additional written permission from the physical access provider to the genetic resource may be needed (e.g. private landowner, indigenous and local communities where they are managers or custodians of the genetic resources).

_____

_____

_____

4.2. **Time and Duration of the project: Please provide a timeline indicating the different phases and respective milestones of the project (can be attached as annex to this application form).**

From:
To:

4.1. What types of commercial and non-commercial returns are you expecting from the Research and/or development?

_____

_____

_____

_____

4.2. What benefits will you bring to the community, institution that provided the biological resources/ information and/or traditional knowledge?

_____

_____

_____

_____

4.3. How do you plan to share these benefits with the providers?

_____

_____

_____

4.4. How will the rights of the biological resources and/or traditional knowledge providers or Malawian partners be protected and how

is their contribution going to be acknowledged.

_____

_____

_____

_____

4.5. How will you keep us updated on ongoing progress in your research and/or development?

_____

_____

_____

4.6. Are details of this project confidential?

YES NO
If yes, regarding which subject matter?
Indicate on what conditions you would be prepared to disclose the confidential information to the Competent National Authority (CNA).

SECTION 5

5.0 Application package completeness check

5.1. Have the following documents been provided together with the application?			
		YES	**NO**
1	A Basic ABS contract attached to this application	☐	☐
2	Access Permit	☐	☐
3	A written Prior Informed Consent from the Provider	☐	☐
4	Research Permit from National Commission for Science and Technology	☐	☐
5	Application for an Export Permit, as applicable from the relevant Institution	☐	☐
6	Project documents and legal information about the applicant	☐	☐

5.2. Please provide any other information about the application

_____

Please Return completed forms of the application to:

The Director

Environmental Affairs Department

Lingadzi House, City Centre

Private Bag 394, LILONGWE, MALAWI.

Declarations

I/ We declare that the information contained in this application form is true and correct, and I/We shall be responsible for any wrong/incorrect information.

By signing below and submitting this application form, I/We agree to it being incorporated as an integral part into the separate Basic ABS Agreement that I/We have to sign and submit with this application form for review and approval by the Competent National Authority. The permit will refer to the application form and the Basic ABS Agreement as its integral parts and they will be attached to it.

If the permit applicant obtains genetic sequence information from the biological resources through digitization or another process, the applicant undertakes not to share such information with any third party, including a publicly accessible database, without identifying Malawi as the origin of the genetic information, and undertakes to include the following statement with any such submission:

This genetic information may be considered to be part of the genetic patrimony of Malawi, the country from which the sample was obtained. Users of this information agree to: (1) acknowledge Malawi as the country of origin in any publications where the genetic information is presented, and (2) notify the Malawi CBD focal point identified at https://absch.cbd.int/ if they intend to use the genetic information for commercial purposes.

I/We am/are authorised to make this declaration for and on behalf of [insert LEGAL PERSON] (if applicant is a legal person).

Signature .... Date.....

Annex 3: Permits required in Malawi to access, and export biological Resources from various Competent National Authorities

Annex 3: Permits required in Malawi to access, and export biological Resources from various Competent National Authorities

Resource	Responsible Institution	Type of permit	Relevant Law or Guide-line
Forestry Resources	Forestry Department, For-estry Research Institute of Malawi	Access permit Export permit	Forestry Act Seed Act
Parks and Wildlife Re-sources CITES –listed Species	Department of National Parks and Wildlife	Access permit Export permit	National Parks and Wild-life Act
Livestock	Department of Livestock and Animal Health	Access permit Ex-port permit	Control and Diseases of Animal Act Protection of Animals Act
Fisheries Resources	Fisheries Department	Access permit Ex-port permit	Fisheries Conservation and Management Act
Agriculture biological re-sources and genetic re-sources listed in ITPGRFA	Ministry of Agriculture	Access permit Ex-port permit	Seed Act, the Farm Feeds, Fertilizer and Remedies Act, the Plant Protection Act and the Noxious Weeds Act
All access for research	National Commission for Science and Technology	Research permit	Science and Technology Act
collections, botanical gardens, herbaria and museums, Agricultural genetic resources not listed in ITPGRFA Community Biological resources Microorganisms Exotic Species	Environmental Affairs De-partment	Import Permit & Export permit	Environmental Manage-ment Act EMA
All other biological re-sources not listed above including use of tradition-al knowledge and/or use of genetic information or any forms of DNA/RNA sequences or sequence data in any format	Environmental Affairs De-partment	Import Permit & Export permit	Environmental Manage-ment Act EMA

Annex 4: Example of Benefits that can be given under ABS

1. Monetary benefits

Monetary benefits may be generated from:

Access fees/fee per sample collected or otherwise acquired; Commercial products; Joint ventures; Joint ownership of relevant intellectual property rights; Milestone payments; Licensing fees in the case of commercialization; Research funding; Royalties; Salaries; Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity; Up-front payments. **Monetary benefits** Monetary benefits may be generated from Access from Research exchange; Research partnerships; Social recognition; Technology transfer to the provider of the biological resources; Training related to biological resource; Publications and Knowledge

2. Non-monetary benefits

Non-monetary benefits may include:

Access to information relevant to conservation and/or sustainable use of biological diversity, including biological inventories and taxonomic studies; Admittance to ex situ facilities of biological resources and to databases; Collaborative activities and research; Contributions to the local economy; Education; Human resources for capacity-building and/or enforcement of access regulations; Institutional capacity-building; Institutional and professional relationships; Joint ownership of relevant intellectual property rights; Knowledge transfer to the provider of the biological resources; Material resources for capacity-building and/or enforcement of access regulations; Participation in product development; Research directed towards priority needs (e.g., health and food security)

Annex 5: Intellectual Property (IP) implications arising from utilisation of Biological Resources for innovation

STAGES OF VALUE CREATION IN ABS		IP IMPLICATIONS
Access to Genetic Resources and/ or Traditional Knowledge(TK)	-Users may use TK from local communities while conducting their research	The User will have to consider if TK was used and how laws can be applied to protect TK holders and share benefits from the use. The specific arrangements made for IP management can influence the overall results of access to GRs and/or traditional knowledge. The aim is to promote innovation through the protection of TK and the sharing of knowledge to the mutual benefit of the holders and users.
Utilisation for commercial or non-commercial purposes	**Basic research:** is experimental or theoretical work to acquire new knowledge for particular application or use.	Consideration to fully acknowledge providers of Traditional or other local Knowledge in case of publications is encouraged
	Applied research: investigation undertaken to acquire knowledge primarily towards a specific, practical aim or objective.	Consideration to fully acknowledge providers of Traditional or other local Knowledge in case of publications is encouraged and determination of the value of that knowledge and extent of recognition and benefit sharing where applicable.
Research and Development (R&D) that can lead to Commercialisation	**Experimental development:** this work is derived from knowledge gained from research and this work contributes towards improving or producing new products or processes. Users that invest heavily in order develop or improve product or process will seek to recover the investments incurred in R&D with the patent system.	Innovation protected by **Patent law** if it meets the requirements of Novelty, Usefulness and Must not be obvious. IP issues to be considered can include entitlement to seek IP rights in inventions and other results of research using biological resources; the ownership and licensing of any such derivative IP; the responsibility for maintaining and exercising IP rights; the arrangements for distributing any financial or other benefits resulting from this derivative IP, and the requirement for the recipient of the resource to report on any IP that is applied for. The User will have to consider whether a Malawian researcher has contributed to the invention in a manner qualifying to be recognized as a co-inventor in the patent.

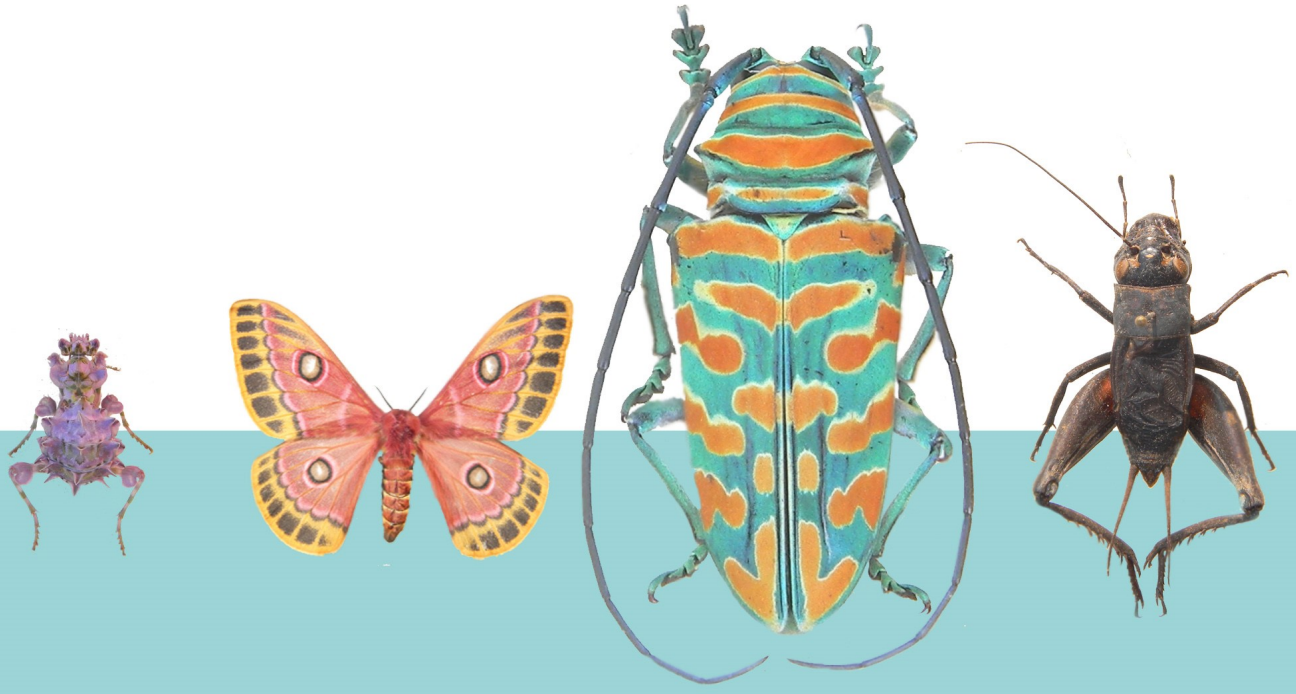
[5] see Vivas Eugui D et al Presentation at UNCTAD's workshop on *"Addressing the intersection between the Nagoya Protocol, ABS*

Third Party Transfer	Transfer of materials/ Knowledge / technology to third parties	If there is intent for third part transfer this may require additional arrangements to be settled between the user and the provider to provide for appropriate mechanisms and distribution of benefits.
Marketing	Promoting of a product or technology to the general public	**Trademarks**: protect any recognisable sign or design associated with product **Collective Marks**: Certifies the individual industrial and manufacturer source of the goods or the services **Geographical Indication**: Protects identification of the origin and its connection with quality and reputation



Photo Credit: WESM

White Fronted bee-eater at Majete National Park



Empowered lives.
Resilient nations.

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Ministry of Natural Resources, Energy and Mining