



NATIONAL ENVIRONMENT MANAGEMENT AUTHORITY



**KENYA'S
ACCESS AND BENEFIT SHARING
TOOLKIT FOR GENETIC RESOURCES
AND ASSOCIATED TRADITIONAL
KNOWLEDGE**

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Acronyms

ABS	Access and Benefit Sharing
ARIPO	African Regional Intellectual Property Office
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CNA	Competent National Authority
CoP	Conference of Parties
DANIDA	Danish International Development Agency
EMCA	Environmental Management and Coordination Act, 1999
GEF	Global Environmental Facility
GIZ	Gesellschaft für Internationale Zusammenarbeit
GM	Genetic Material
GoK	Government of Kenya
GPS	Global Positioning System
GR	Genetic Resources
IIN	Indigenous Information Network
ILCs	Indigenous Local Communities
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
KALRO	Kenya Agricultural and Livestock Research Organization
KEFRI	Kenya Forest Research Institute
KEPHIS	Kenya Plant Health Inspectorate Service
KFS	Kenya Forest Service
KIPI	Kenya Industrial Property Institute
KNBSAP	Kenya National Biodiversity Strategy and Action Plan, 2000,
KWS	Kenya Wildlife Service
LCs	Local Communities
MAT	Mutually Agreed Terms
MEAs	Multilateral Environmental Agreements
MTA	Material Transfer Agreement
NACOSTI	National Commission for Science, Technology and Innovation
NEMA	National Environment Management Authority
NMK	National Museums of Kenya
PAs	Protected Areas
PIC	Prior Informed Consent
PIN	Personal Identification Number



TK Traditional Knowledge
UNEP United Nations Environment Programme
UoN University of Nairobi



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Foreword



The National Environment Management Authority (NEMA), was established under the Environmental Management and Co-ordination Act (EMCA) 1999. Its mandate is to coordinate and supervise all matters relating to the environment in Kenya and to be the principal instrument of government in the implementation of all policies relating to the environment.

The Constitution of Kenya, 2010 (Article 69(1)) has obligated the State to ensure sustainable, exploitation, utilization, management and conservation of the environment and natural resources and, ensure the equitable sharing of the accruing benefits. The issues of ABS are also provided for under the Environment Management and Co-ordination Act, 1999, (Conservation of Biological Diversity and Resources; Access to Genetic Resources and Benefit Sharing) Regulations 2006 (often called “the ABS Regulations, 2006”) and other relevant national laws and policies. NEMA works closely with lead agencies in development and implementation of ABS policies and legislation in the country.

For decades, both public and private institutions have freely accessed and collected genetic resources (GR) and associated traditional knowledge (TK) from Kenya subsequently, utilizing them in the development of various products such as pharmaceuticals, food and beverages, medicines, cosmetics just to name a few. They have proceeded to exclusively own the resultant innovations, without sharing the benefits with the source communities and the country, and in total disregard of relevant international conventions on access to such resources. NEMA has over the last few years taken several initiatives and measures to ensure sustainable development and utilization of the country’s GR. In order to strengthen implementation of the ABS Regulations, the Authority mandated a team of experts to develop this user-friendly toolkit that will assist providers and users of genetic resources, local communities as well as policy makers, regulators and checkpoints in monitoring utilization of genetic resources.



It is envisaged that this Toolkit will provide guidance, standardize access procedures and enhance capacity of all players to ensure fair access to genetic resources and equitable sharing of accruing benefits arising from sustainable use of biodiversity for the development of this country.

Prof. Geoffrey Wahungu
Director General
National Environment Management Authority



Executive Summary

Genetic Resources (GR) are the bedrock of Kenya's economy, particularly as the nation seeks to create wealth, sustain food security and maintain a safe environment. This necessitates increased development of expertise, enhanced research, equitable and sustainable use of our genetic resources. But to succeed in this mission, many different stakeholders including lead agencies, academia, industry, government local communities and others must act in ways that maximize synergy and complementarily to ensure sustainable use and development such that the benefits arising from the use of these genetic resources are shared equitably.

Currently, the development, use and regulation of GR and/or associated traditional knowledge (TK) in Kenya is governed by the ABS Regulations, 2006. Despite the existence of this subsidiary law, Kenya lacks a standard Toolkit and protocols upon which the ABS Regulations on sharing of the benefits arising from the use of Kenyan GR. For this reason, the Authority in liaison with lead agencies has developed a toolkit using the services of Annifri Services Consultants based in Nairobi. The toolkit will stimulate, development of, and support a national research agenda as well as strengthening adherence to Genetic resources access and benefit sharing Regulations in the country.

In this Toolkit, Chapter I briefly describes the genetic resources of Kenya, laying the foundation for the discussion on ABS. It broadly presents the standard practices of accessing the GR and TK. It outlines the steps taken by Kenya to domestic the international instruments of access and benefits sharing and underscores the importance of legal access. Finally, it states the objectives and identifies the gap in ABS implementation filled by the development of this toolkit.

Chapter II describes the methodology used in the development of this toolkit, briefly mentioning, the steps involved and the process and the scope and general guiding principles applicable to the toolkit.

Chapter III deals with the main ABS stakeholders, identified as the users, the providers including the communities and the regulators and each having specific roles.



In Chapter IV, the toolkit describes the necessary tools i.e. negotiated documents for preparing for access to and sharing the benefits accruing from gaining access to GR and TK. It describes the tools and the necessary ingredients.

In Chapter V, the toolkit provides the stepwise process namely; pre –access, access permit procedures and post-access procedures. It helps the applicant follow the process in a stepwise manner and provides timelines in assessment for and granting of access.

Chapter VI deals with a number of procedures and responsibilities to be undertaken by providers and permit holders of GR after access including execution of MTA and the role of checkpoints.



CHAPTER I: INTRODUCTION

This Chapter briefly describes the genetic resources of Kenya, laying the foundation for the discussion on ABS. It briefly outlines the concepts of ABS and domestication of the international instruments of access and benefit sharing.



Plate 1.1 Some Genetic Resources in Kenya



1 BACKGROUND INFORMATION

1.1 Access and Benefit Sharing Concept

Access and benefit-sharing (ABS) is an established international system that spells out the way in which genetic resources and associated traditional knowledge (TK) are accessed, and how the benefits that result from their use are shared between the users and the providers. The concept of access and benefit sharing was coined during negotiations and signing of Convention on Biological Diversity (CBD) in 1992. In its third objective, CBD requires all contracting parties to ensure fair and equitable access to genetic resources and sharing of benefits accruing from utilization of genetic resources and associated TK (Thomas Greiber *et al*, 2012).

Under the concept of ABS, genetic resources refers to genetic material of actual or potential value whereby genetic material is understood to mean material of plant, animal or microbial or other origin containing functional units of heredity. Usually, such uses of genetic resources range from basic research that provides a better understanding of the world's natural resources to development of commercial products that spur economic development. Genetic resources can be wild, domesticated or cultivated. "In situ" genetic resources are those found within ecosystems and natural habitats (Evanson Chege Kamau *et al*, 2010. "Ex situ" genetic resources are those found outside their normal ecosystem or habitat, such as in botanical gardens, university collections, gene banks, public research laboratories, or in commercial collections.

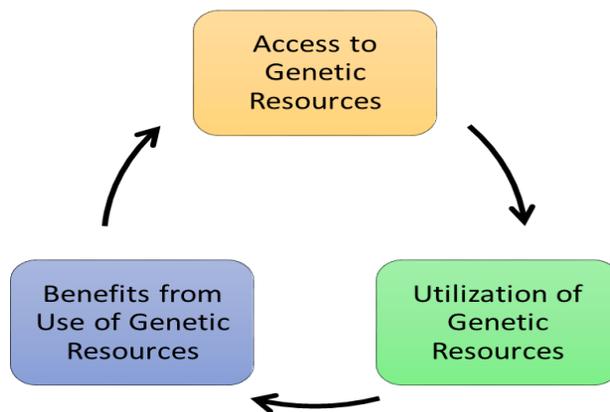


Figure 1.1: Illustrated ABS Concept



Benefit Sharing refers to the distribution of benefits that accrue from the utilization of genetic resources and associated traditional knowledge, practices and innovations. The benefits include both monetary and non-monetary returns. Monetary benefits include up-front payments, royalties and salaries while non-monetary benefits cover institutional development, training, technology transfer and information exchange.

1.2 Kenya's Genetic Resources

Kenya is home to over 34,000 species of flora and fauna found in national parks, nature reserves and private nature conservancies (KNBSAP, 2000). It is a world destination for business and leisure, renowned for its abundant natural and cultural heritage as well as diverse ecosystems and landscapes. Local biodiversity conservation remains one of the country's top priorities. In addition, to the rich biodiversity, Kenya is a multi-cultural society, with high level of TK, a wide variety of traditional cuisines and food culture, medicinal plants among other heritage resources.

Kenya is also regarded as the cradle of humankind due to the rich prehistoric fossil findings including several hominid fossil species that comprise some of the most complete skeletons dating millions of years back. Thus, Kenya attracts researchers interested in GRs and TK for research and development. However, these same conditions result in TK leakages or biopiracy of unknown value. Hence, the need to provide a simple and user-friendly access and benefit sharing toolkit.

1.3 Access to Kenya's Genetic Resources

For decades, both public and private companies have freely accessed and collected genetic resources (GR) and associated traditional knowledge (TK) from Kenya. They have utilized them for various purposes such as pharmaceuticals, food and beverages, biotechnology, seed, crop protection, horticulture, botanicals, medicines, cosmetics and personal care. In some cases these companies have owned the resultant innovations, without due regard to the source community and Kenya. This act of searching for leads and gathering of biological material of potential value is bioprospecting. When bioprospecting takes place without the knowledge of source country or local/indigenous community and without



compensation, the activity is referred to as biopiracy (Mukonyi *et al*, 2010). As aggregates of actual or potential value, biodiversity resources and associated TK need to be safeguarded for both posterity and socio-economic development.

1.4 Traditional Knowledge Associated with GR

The issues of traditional knowledge are drawn from Article 8(j) of the CBD which requires each Contracting Party, to enact national legislation to give effect to respect, preserve, promote as well as encourage equitable sharing of benefits derived from utilization. The spirit in the Article is that TK, innovations, and practices on animals, plants, insects, or ecosystems can provide interesting leads to and an initial screen for isolating particular properties of genetic resources found in nature. Consequently, TK has guided a number of companies in the development of new products (Laird and Wynberg, 2008).

The traditional or indigenous knowledge of Kenya's diverse communities associated with utilization of biodiversity and GR is part of her heritage and resources for national development and the ABS Regulations classify TK as intangible component of the resources.

TK is lost through various means including workshops, herbaria collection, publications and sharing of information with local communities.





Plate 1.1: Sources of loss of TK associated with GR in Kenya

1.4.1 Community Protocols

Community protocols (CPs) are an emerging concept in access and benefit sharing policy framework. They encompass a broad range of practices and procedures, both written and unwritten, developed by Indigenous Local Communities (ILCs) in relation to their TK, territories and other resources. In Kenya, these practices and procedures cover a range of matters, including how ILCs expect external actors to engage with them especially during negotiation for Prior Informed Consent (PIC) as part of the process of accessing GR and TK (Barbara Lassen, 2012).



Plate 1.2: Community Protocol Sensitization Meeting

1.5 International Framework

Access and benefit sharing mechanisms are stipulated under Articles 15 and 8(j) of the CBD (1992). CBD provides a global set of principles for access to genetic resources, as well as the fair and equitable distribution of the benefits that result from their use.

In 2002, the Bonn Guidelines were adopted by the Conference of the Parties (CoP) to the CBD as voluntary guidelines intended to assist governments in the adoption of measures to govern access and benefit-sharing in their countries. The guidelines outline the key steps in the ABS process, including the basic elements required for PIC and Mutually Agreed terms (MAT). It also outlines the main roles and responsibilities of users and providers, and includes a list of monetary and non-monetary benefits that can arise from the use of genetic resources (Bonn Guidelines, 2002).

In 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) was adopted as a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of the third objective of the CBD. The objective



of the Protocol is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity. Kenya acceded to the Protocol in May, 2014 and the Protocol came into force Pyeongchang, South Korea on 12th October, 2014.

1.6 Legal and Institutional Framework

Kenya is in the process of domesticating the Nagoya Protocol. In this regard, it is expected that the government will designate the focal point, competent national authorities, checkpoints, publishing authorities and the clearing house mechanisms.

In Kenya, the Access Permit is issued by NEMA under the ABS Regulations, 2006 developed vide section 53 of EMCA, 1999. The Regulations are supplemented by other legislations administered by lead agencies. They provide for issuance of access permit by NEMA which is subject to provision of research licence, PIC granted to a user by a provider based on MAT.

Prior informed consent is provided by a lead agency, local community or private resource manager. In the last two cases, the relevant lead agency must participate in the negotiations for MAT. Research licence is issued by the National Commission for Science, Technology and Innovation (NACOSTI) upon submission of letter of intent, researcher pass (for foreigners) and letter of affiliation to a local institution.

Where the user intends to transfer genetic resources, another agreement referred to as Material Transfer Agreement (MTA) must be executed. MTA is fully negotiated and concluded between the provider and user witnessed by relevant lead agency or local community.

1.6.1 Lead Agencies and Competent National Authorities

Under EMCA, a lead agency means any government ministry, department, parastatal, state corporation or local authority, in which any law vests functions of control or management of any element of the environment or natural resources. Currently, lead agencies performs functions of competent national authorities. Technically, these are bodies established by the government and which in liaison with NEMA are responsible for:



- i. Granting PIC, research licence, pass or letter of affiliation to users of genetic resources,
- ii. Negotiating for MAT, MTA and benefit sharing agreements with users of GR,
- iii. Advising users and providers on various aspects of ABS, and
- iv. Serve as checkpoints in monitoring compliance with ABS requirements.

Implementation measures on how lead agencies work are spelt out in the National ABS Regulations. Table 1 below, is a list of examples of lead agencies in Kenya:-

Table 1.1: Selected Lead Agencies in Kenya

S.NO.	LEAD AGENCY	MAIN ROLE
1.	Kenya Wildlife Service (KWS)	Management of wildlife genetic resources, and issuance of PIC, MAT and export permit
2.	Kenya Forest Service (KFS)	Management of forest genetic resources and associated biodiversity
3.	Kenya Plant Health Inspectorate Service (KEPHIS)	Issuance of Phyto-sanitary Certificate and administration of plant breeders' rights
4.	Kenya Agricultural and Livestock Research Institute (KALRO) through the National Gene bank	Management of <i>ex-situ</i> plant genetic resources accessed under the ITPGRFA Protocols
5.	National Museums of Kenya (NMK)	Management of cultural heritage, natural history collections and GRs obtained from monuments and heritage sites.
6.	Kenya Medical Research Institute (KEMRI)	Management of human GRs and related biodiversity
7.	Department of Veterinary Services	Animal Health Certificate
8.	Public Universities & Other Public Research Institutes	Issuance of Letter of Affiliation and conclusion of Collaborative Research Agreements or MOUs
9.	Department of Immigration	Issuance of Researcher Pass
10.	National Commission for Science, Technology & Innovation (NACOSTI)	Issuance of Research Licence



11.	National Intellectual Property (IP) Offices	Management of Intellectual Property Rights (IPRs) as checkpoints
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1.7 The ABS Challenge in Kenya

Experience in the past four years of ABS permitting in NEMA has shown that individuals have trouble while seeking to access the biological/genetic resources or the associated knowledge for research or commercial purposes due to various licenses/permits issued in the country by various government institutions. In most instances one does not know where to start and where to move to next and finally where to end or information on requirements of obtaining such licenses/permits. In general there is uncoordinated ABS legal framework lack of ABS policy framework and lack of awareness on ABS policy among the various stakeholders.

For decades, both public and private companies have freely accessed and collected GR and associated TK from Kenya. They have utilized them for various purposes such as pharmaceuticals, food and beverages, biotechnology, seed, crop protection, horticulture, botanicals, medicines, cosmetics and personal care. In some cases these companies have owned the resultant innovations, without due regard to the source community and Kenya. This act of searching for leads and gathering of biological material of potential value is bio-prospecting. When bio-prospecting takes place without the knowledge of source country or local/indigenous community and without compensation, the activity amounts to bio-piracy.

Due to these challenges the permits issued have been few though increasing year by year at low numbers. This underscores the need for this ABS information toolkit for information dissemination and awareness.

1.8 Objectives and Purpose of this Toolkit

1.8.1 General Objective

This toolkit is meant to ensure that the applicant for access to GR or potential user, provider and lead agencies have the necessary information to enable them adhere to established standards of procedure when accessing or providing GR.



1.8.2 Specific objectives

The specific objectives of this toolkit are to:-

1. Document standard procedures for accessing GR and TK in Kenya,
2. Document procedures and mechanisms for sharing benefits accrued from genetic resources in Kenya, and
3. Create awareness and enhance capacity of stakeholders in ABS in Kenya.

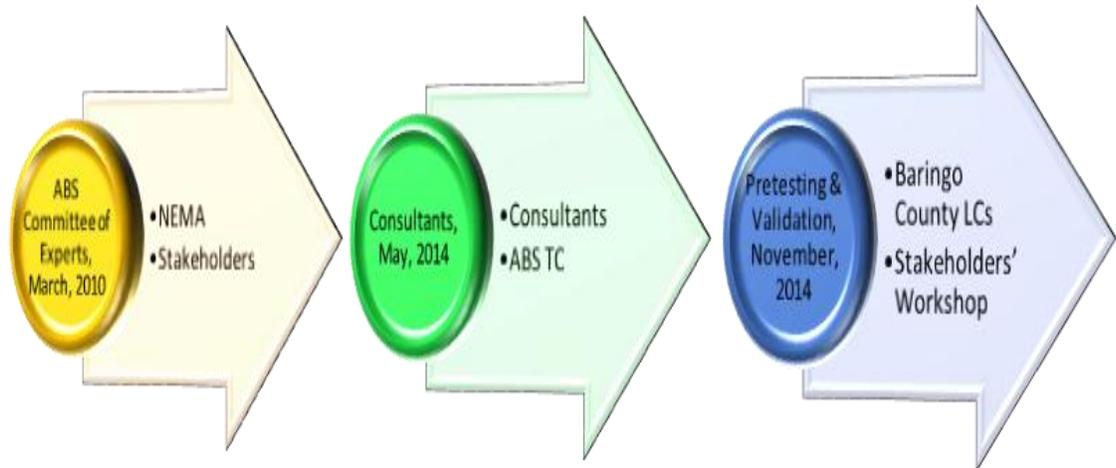
1.8.3 Purpose

The purpose of the toolkit is to create awareness among users and providers of genetic resources, inform about the systems which are in place governing the access to genetic resources and/or associated knowledge and standardize access and benefit sharing guidelines as established in EMCA, 1999 and the ABS regulations, 2006.



2 CHAPTER II: METHOD FOR DEVELOPMENT OF THE TOOLKIT

Chapter II describes the method used in the development of this toolkit, briefly mentioning, the steps involved, the process, the scope and general guiding principles applicable to the toolkit.



2.1 The Process

The process for development of this tool kit involved various approaches including desk review of documents, consultative meetings, field validation and stake-holder workshops.

The process commenced with a taskforce of experts from NEMA and relevant lead agencies including representation from indigenous community that was appointed to prepare the ABS Guidelines. The consultative process commenced in March 2010 and thereafter meetings and workshops were held in April, June and November, 2012 and in February, 2013.

This was followed by a process of review starting with 'mapping' relevant documents in the area of access to genetic resources and indigenous knowledge in Kenya by the Consultant in May 2014. Legal instruments governing access to biodiversity resources including international and regional instruments were reviewed (Appendix V). It then proceeded with their analysis while benchmarking with best practices in the region. In addition, the consultant established that there was no *de facto* moratorium or prohibition on access to GR and TK in Kenya. Further, the consultant scrutinized the instruments and established that there indeed existed processes for formal requests for access and use through pre-existing permitting systems as well as the law of contract for conflict resolution.

By drawing attention to the relevant documents in an integrated manner, this toolkit promotes a process of legal exploration of ABS in the widest sense and eliminates boundaries caused by subjective interpretation of the provisions. As such, the annexure promotes dialogue about the key issues among all the ABS players, notably the Authority, lead agencies, local communities and the parties interested in GR and TK in Kenya.

The draft document received comments and input from the ABS – TC during consultative meetings. Field pre-testing (plate 2.1) of the tool kit was done in focus group discussions aided with a check-list. Finally, a national stakeholders' validation workshop was held on 7th November, 2014 to obtain further inputs which were incorporated into this document.



Plate 2.1: Members of the Consulting team, ABS-TC and local community during the pre-testing of the draft Toolkit in Baringo County

2.2 General Guiding Principles

In order to ensure harmony in the development of the toolkit as presented, the following general principles guided the process;

- i. Regulation of access to GR and associated TK;
- ii. Fair and equitable sharing of benefits accruing from the utilization of GR and associated TK;
- iii. Sustainable economic growth that empowers the current generation and safeguards the future generation;
- iv. Conserve, protect and commercialize use of GR and TK through legal bioprospecting and biotrade;
- v. Protection of IP of local communities;
- vi. Collaboration and partnerships in research and development using Kenya's GR and associated TK.



2.3 Target Groups

This toolkit is intended for use by the providers, users, local communities and regulators of GR and associated TK. For GR users, it helps in adopting a standard ABS practice for legal access and for providing fair and equitable benefit sharing from the use of GR. It also assists GR providers to make informed decisions about facilitating the legal access and manage their expectations in negotiating access to and use of GR and TK with the users. For regulators, it provides the important steps and acceptable practices in ABS and serve as a capacity-building tool.



CHAPTER III: ABS STAKEHOLDERS

This Chapter highlights the main ABS stakeholders identified as the users, the providers (including the communities), checkpoints, regulators among others.

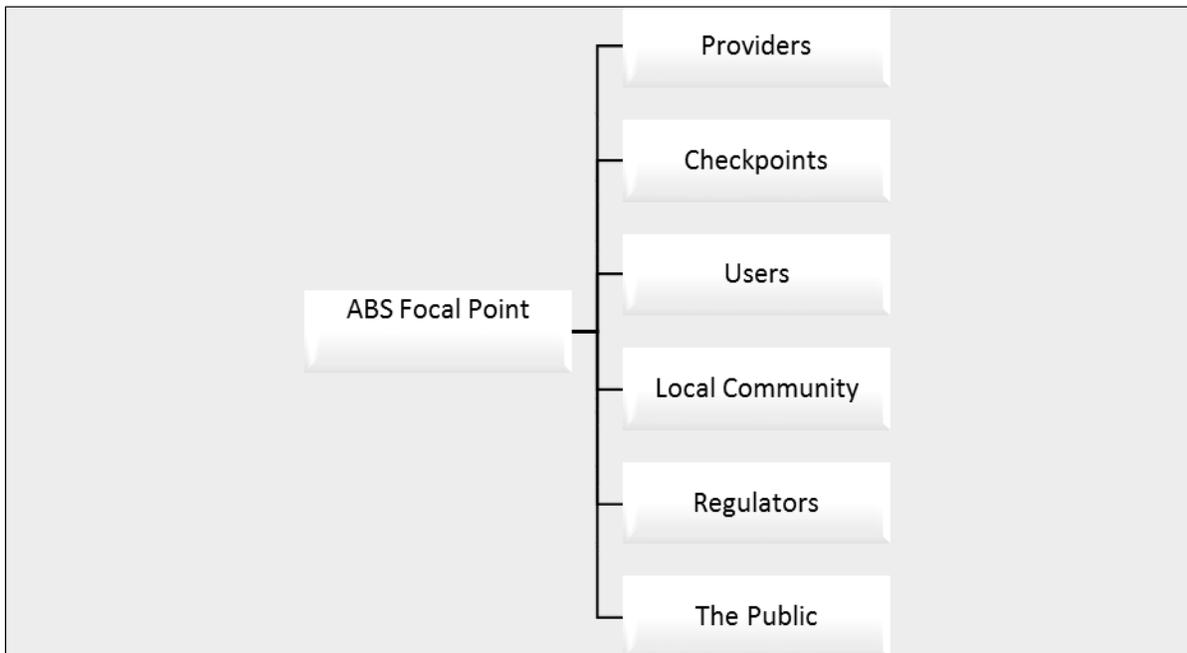


Figure 3.1: Illustration of ABS Focal Point and Stakeholders



The main stakeholders involved in ABS regime are: providers, users, lead agencies, local Communities and checkpoints. The figure 3.1 above demonstrates the relationship between various stakeholders involved in ABS System.

3.1 Providers of Genetic Resources

The overall ownership of genetic resources is vested in the State. In Kenya, there are key genetic resource providers and lead agencies who negotiate and issue PIC and MAT as illustrated in table 3.1 below.

Table 3.1: Categories of Genetic Resource Providers in Kenya

S. NO.	GENETIC RESOURCE PROVIDER	DESCRIPTION
1	Local Community	Local and indigenous communities or Community-based Organizations (CBOs) in possession of knowledge or occupying areas of jurisdiction, ancestral domains or land on the bioprospecting and collection of genetic resources is undertaken e.g. the Ogiek in Mau and Mijikenda in Kayas. They are also in charge of their own community protocols during access. During negotiation for PIC, the relevant lead agency is involved.
2	Public Resource Managers	National Government Institutions in-charge of <i>in-situ</i> conservation of wildlife, forest or marine protected areas where prospecting of biological and genetic resources is undertaken e.g. KWS and KFS. During negotiation for PIC, the affected communities are involved.
		County Government land and genetic resource managers' in-charge of management of game, forest, land and marine reserves where bioprospecting and collection of genetic resource take place e.g. Narok County. During negotiation for PIC, the affected communities are involved.





3	Private Resource Managers	Individual and corporates owning private land, practising wildlife conservation and other forms of genetic resources where bioprospecting is undertaken e.g. private wildlife ranches such as Lewa Conservancy. During negotiation for PIC, the relevant lead agency is involved to issue a letter of support.
4	<i>Ex-Situ</i> Conservation Resource Managers	<i>Ex-situ</i> conservation public and private genetic resource facilities in which prospecting of biological and genetic resources is undertaken such as National Gene Bank, Zoos, Botanical Gardens, International Agricultural Research Centres (IARCs), Consultative Group of International Agricultural Research (CGIARs) and Non-Governmental Organizations (NGOs). During negotiation for PIC, the relevant lead agency is involved to issue a letter of support. <i>Ex-situ</i> resource providers must aspire to disclose the original source of the material or resource as part of the negotiations.



Plate 3.1 and 3.2 below illustrates some of the sources of GR.

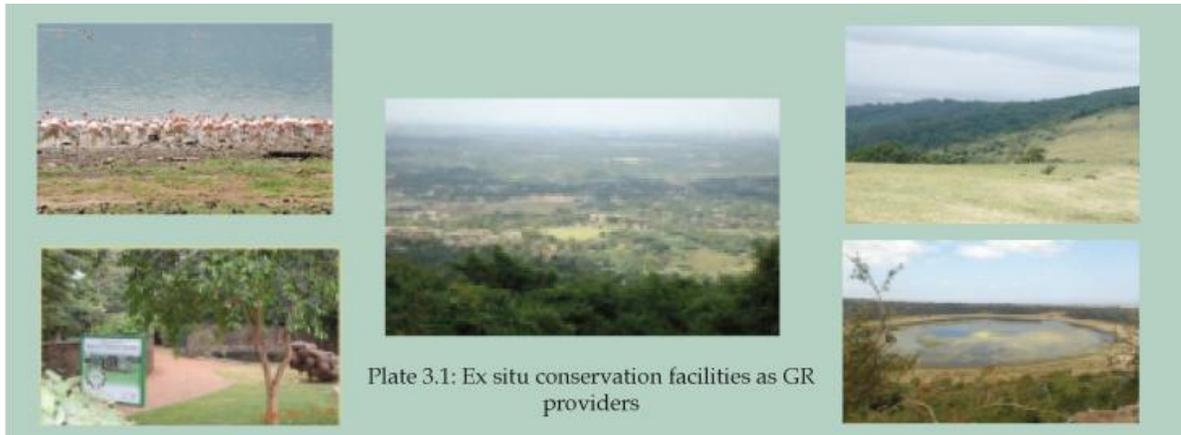


Plate 0.1: Ex situ conservation facilities as GR providers

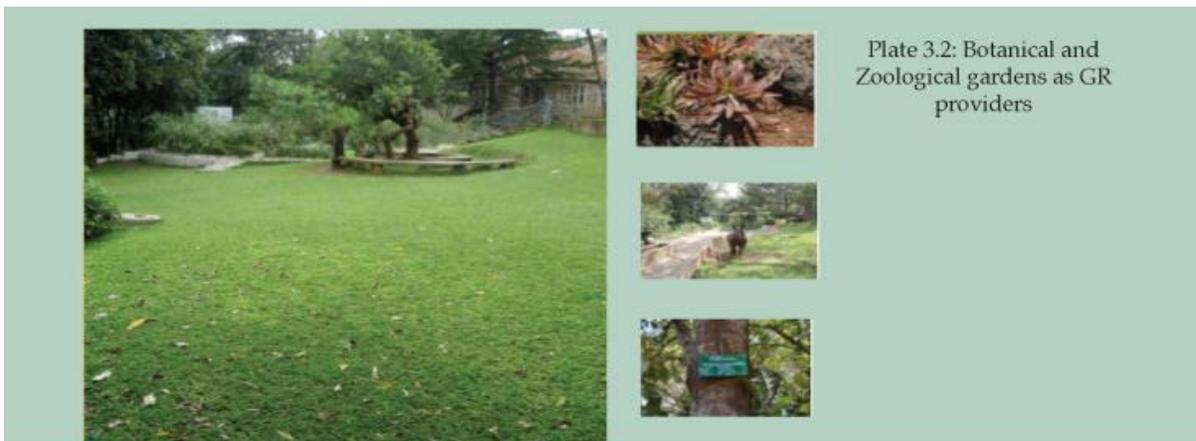


Plate 0.2: Botanical and Zoological gardens as GR providers

3.1.1 Obligations of Providers

It is the obligations of GR providers to:

- i. Understand the requirements for PIC and MAT,

- ii. Negotiate PIC and MAT with the user prior to granting access of the genetic resource and/or associated traditional knowledge,
- iii. Collaborate and consult with a relevant lead agency/ies in providing the genetic resource, and
- iv. Renegotiate PIC and MAT (where applicable) during variation of the access permit.

3.2 Users of Genetic Resources

According to ABS Regulations 2006, anyone pursuing collection activities in Kenya, whether of tangible materials or intangible information is a 'user' and is required to apply for an access permit from NEMA. Users are diverse, but few groups can easily be singled out including scientists, researchers, curators, bio-prospectors and investors who make significant use of proprietary genetic resources, biological material and related information including genetic information, traditional knowledge and farming know-how.



Plate 3.3: Researchers accessing genetic resources in Ngong hills and Marsabit forests

Users seek access to genetic resources for a wide range of purposes, from basic research to the development of new products. They are a diverse group, including botanical gardens, industry researchers such as pharmaceutical, agriculture and cosmetic industries.

Users of genetic resources



Public facilities, Chenshan Botanic Gardens China 2014 © A. Lusweti



Biotech companies, source; www.bio.org, accessed 08-08-2014



Biotech companies, source; www.biotech-products.com, Accessed 08-08-2014



Research institutions, Varieties of pearl millet, © P. Maundu, 2012



Research and development, Naturub® source; www.proudlymadeinafrica.org, accessed 02-09-2014

Plate 3.4: Pictures of applied use of GR materials

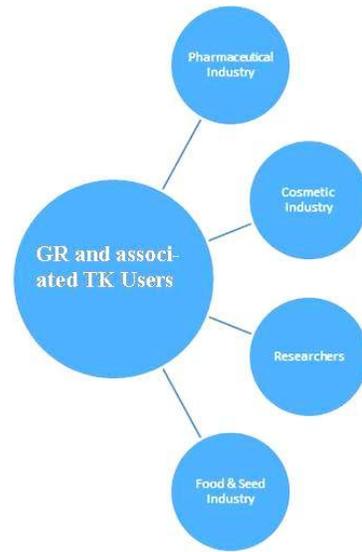


Figure 3.2: An illustration of some users of GR and associated TK

3.2.1 Obligations of the User

Genetic Resource users are obliged to:

- i. Establish a collaboration with local partner during access to the genetic resource,
- ii. Apply for access permit from NEMA prior to accessing genetic resource(s) and disclose information on any known or potential use of the material to be accessed
- iii. Facilitate the provider(s), NEMA and lead agencies with information and data pertinent and resulting from the utilization of the genetic resources including derivatives
- iv. Meet all costs incidental to the access, including technology transfer and reporting
- v. Use the GR and/or associated TK as specified in PIC and MAT.
- vi. Renegotiate the PIC, and MAT (where applicable) and apply for a variation of the access permit, if s/he intends to vary the use of the GR and or its derivatives in the initial PIC and MAT.



3.3 ABS Checkpoints

With the coming into force of Nagoya Protocol, it is expected that the country will designate checkpoints through an appropriate legal instrument. Currently, the role of checkpoints is being played by NEMA and lead agencies charged with issuance of permits and approvals for monitoring compliance with the relevant agreements and application of ABS tools by both user and provider.

3.4 The Public

The public is involved in the ABS process in line with the principle of public participation, a national value and principle of governance. In this regard, NEMA publishes the permit applications in the Kenya Gazette and in local dailies with nationwide circulation and invites comments on the material that is proposed to be accessed. Those comments are considered and reviewed by the technical committee before grant or decline of the permit. In addition, public is also provided with various avenues for grievance resolution which they could explore where they feel aggrieved. They include, traditional dispute resolution mechanisms, the National Environment Tribunal, the Environment and Land Court, the High Court among others.

3.5 Local Community

The local communities are custodians of TK and GR within their jurisdiction and are responsible for sustainable exploitation, management and conservation. LCs are required to develop and oversee the observance of bio-cultural community protocols during negotiation for PIC and access to the GR and TK by the user. They are responsible for ensuring the accrued benefits are for the common good of the whole community.





Community members in discussion, 2014 © A. Lusweti, NMK

Plate 3.5: Local community in discussion of bio-cultural protocols

3.6 Regulators

These are lead agencies that issue permits and approvals or have direct role in regulating ABS in the country. These are NEMA, NACOSTI, KWS, KEPHIS, DVS among others.

CHAPTER IV: THE ABS TOOLS

This chapter describes the necessary tools i.e. negotiated documents for preparing for access to and sharing the benefits accruing from gaining access to GR and TK.



Plate 4.1 Pictures of ABS information tools

4 TOOLS IN ABS KIT

There are various tools in the implementation of the ABS. The most used tools are; PIC, MAT, MTA, Benefit Sharing Agreements and Reports on utilization. These tools are crucial among important target groups of diverse stake-holders including GR providers, potential users or applicants, lead agencies, communities, researchers and collaborators. It is therefore important to henceforth avail to applicants for access to GR information on required documents, provide samples and underscore the role of key players and institutions such as the focal institutions and competent national authorities. PIC, MAT and MTA are required for the user to gain legal access to GR and TK in Kenya. Other tools are embedded in benefit sharing related MoUs.

4.1 Prior Informed Consent

Prior Informed Consent (PIC) is the permission given by the provider or competent national authority of a provider country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework. It is the main ABS tool that is usually negotiated between the provider and the user of GR through an agreement involving mutually agreed terms (MAT). In Kenya, PIC is a written document and granted upon completing a Form modelled along Appendix I of the ABS Toolkit. PIC requires the user to disclose contact details, local affiliate, project type, location and nature of genetic resources to be accessed, method of collection, role of local community or lead agency, benefit sharing mechanisms and declaration of accrued benefits. It is the duty of the potential GR user to make full disclosure to the provider so as to make informed decision to grant access or not. In Kenya, PIC is a negotiated document (See appendix I) by parties and requires minutes of meetings with community or letter of support from lead agency.

4.2 Mutually Agreed Terms

Mutually Agreed Terms (MAT) is an agreement reached between the providers of genetic resources and users on the conditions of access and use of the resources, and the benefits to be shared between both parties. This agreement is negotiated in the presence of relevant lead agencies to ensure a fair access and equitable sharing of the benefits. In Kenya, MAT is

a negotiated agreement by parties and requires minutes of meetings with community, permit, licence or letter of support from relevant lead agency as modelled in Appendix II.

4.2.1 *Negotiating PIC and MAT*

Typically, negotiation will be on the following issues:

- a) Type and quantity of GRs,
- b) Geographical/ecological area of activity,
- c) Any limitations on the possible use of the material proposed to be accessed,
- d) A clause addressing whether the terms of the agreement, in certain circumstances, could be renegotiated,
- e) Whether the GRs can be transferred to third parties and conditions to be imposed in such cases,
- f) Provisions regulating the use of resources in order to take into account ethical concerns of the particular parties and stakeholders,
- g) Cultural protocols assigning proprietary value to traditional know how of the local communities
- h) Treatment of confidential information
- i) Provisions regarding the sharing of benefits arising from the commercial and other utilization of GRs and their derivatives and products or services and this should be represented in a benefit sharing plan
- j) Capacity building in various areas to be identified in the agreement
- k) Dispute resolution mechanisms
- l) Ownership of intellectual property rights

4.3 *Material Transfer Agreement*

Material Transfer Agreement (MTA) is an agreement negotiated between the holder of an access permit and a relevant lead agency or community on terms of transfer and use of genetic material (Appendix III). In circumstances under which the project is designed to export GR out of Kenya, the applicant is required to execute MTA with relevant



government institution or community. MTA is a requirement for grant of an export permit or licence.

4.3.1 Contents of Material Transfer Agreement

A typical MTA should contain the following clauses:

- a. A preamble statement providing context,
- b. A definition of the material to be transferred,
- c. Justification for transfer,
- d. User and provider obligations,
- e. Purpose or use: taxonomy, collection, research, commercialization and expected outputs,
- f. Restrictions and stipulations on how it will be used,
- g. Commencement and termination dates,
- h. Termination clauses,
- i. Ownership of IPRs,
- j. Applicable law,
- k. Fate of genetic material after the project life,
- l. Treatment of confidential information
- m. Dispute resolution provisions, and
- n. Benefit sharing arrangements.

4.4 Information Transfer Agreement

Information Transfer Agreement (ITA) is used to exchange traditional knowledge information and data associated with genetic resources. This is used where the users need not to access the genetic material.

4.5 Benefit Sharing Plan

Benefit sharing refers to an arrangement between provider and user of GR on how they will distribute benefits accruing from utilization of GR. In Kenya, the holder of an access permit



is responsible for ensuring the provider's enjoyment of both monetary and non-monetary benefits arising from the proprietary rights of access and the use of GR as illustrated in Figure 4.1 below.

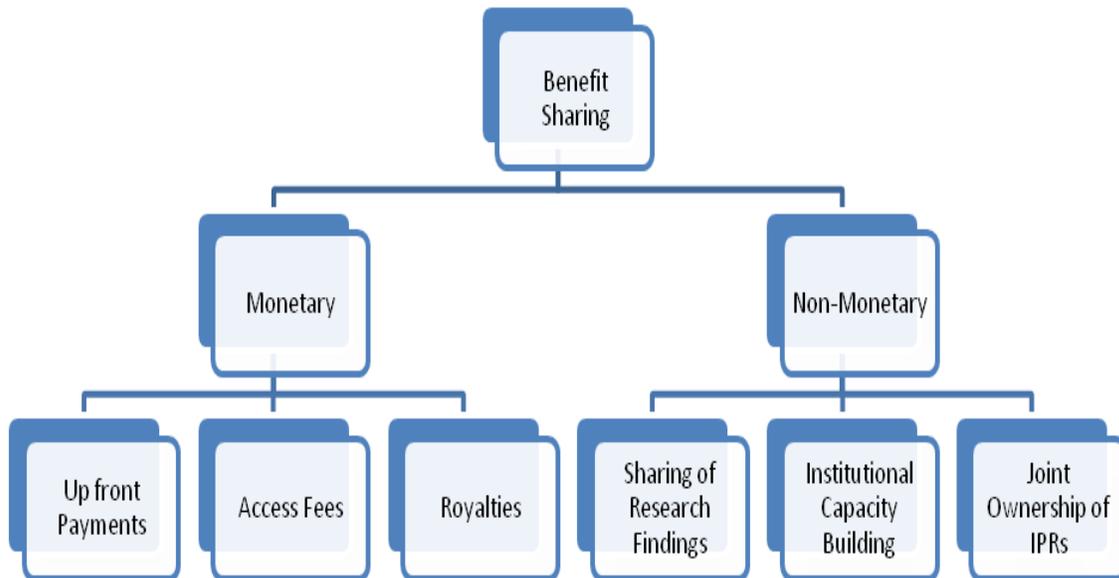


Figure 4.1: Types of ABS Benefits

4.5.1 Monetary Benefits

Monetary benefits consist of any or a combination of the following:

- a) Access fees or fee per sample collected or acquired;
- b) Upfront, license fee, milestone and royalty payments;
- c) Fees to be paid to trust funds for supporting conservation and sustainable use of biodiversity;
- d) Salaries and preferential terms where mutually agreed;
- e) Research funding and joint ventures;

- f) Joint ownership of relevant intellectual property rights;

4.5.2 *Non-monetary Benefits*

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

- a. Sharing of research and development information as well as technology transfer under fair and most favorable terms,
- b. Admittance to *ex-situ* facilities of genetic resources and access to databases by participating institutions,
- c. Human and institutional capacity building;
- d. Access to scientific information relevant to conservation and sustainable use of biological diversity,
- e. Institutional and professional relationships arising from access and benefit sharing agreements and subsequent collaborative activities,
- f. Acknowledgement in Public Journals and other publications,
- g. Joint ownership of relevant intellectual property rights.

CHAPTER V: ACCESS PERMIT PROCEDURE

In this chapter, the toolkit provides the stepwise process namely; pre –access, access permit and post-access procedures. It helps the applicant follow the process in a systematic manner and provides timelines in assessment for and granting of access.



Plate 5.1: Access to Aloe sp. in Ex-Situ Conservation

5 ACCESS PERMIT PROCEDURE

This procedure is directed to the user of genetic resources. It is categorized into three phases namely; pre- access, access and post-access procedures.

5.1 Pre-Access Procedure

Pre-access procedure concerns mainly the acquisition of requisite documents for filing an application for the access permit. These are:

5.1.1 Identification of Local Partner

Prior to travel for purposes of research, the applicant is required to identify and contact counterparts in Kenya. It may be necessary to visit NEMA's website at www.nema.go.ke to find out which rules apply on access to GR. Similarly the applicant is advised to visit NACOSTI website at www.oris.nacosti.go.ke or www.nacosti.go.ke on application for research license. The applicant is also required to negotiate terms and conditions of the memorandum of understanding (MOU) or equivalent collaborative framework with the Kenyan counterpart working with a lead agency. He may sign MOU and seek a letter of affiliation from the collaborating institution.

5.1.2 Identification of GR Provider

In liaison with the local counterpart in Kenya, the applicant is required to identify a potential GR provider and/or associated TK. The provider may be a Lead agency, individual or community in a specified locality in Kenya. If the applicant plans to carry out a collaborative research with his/her local counterpart, it is recommended that a joint proposal is developed at this stage.

5.1.3 Application for Research License

The applicant shall apply for research license from NACOSTI online in accordance with the Science, Technology and Innovation Act, 2013. The following documents shall be required to be attached to the application Form for Research License:

- a) Letter of Affiliation from local counterpart
- b) Partnership MOU, and
- c) Project proposal abstract.

For applications requiring research licence the permit will be issued by NACOSTI within seven (7) days for local researchers. However, it will take fourteen (14) to thirty (30) days for collaborative research involving foreigners and local researchers studying outside the country. The licence shall be required by the Department of Immigration and NEMA to facilitate issuance of a researchers' pass or visa and access permit respectively.

5.1.4 Acquisition of Researcher's Pass

Upon receipt of a research licence from NACOSTI, the applicant shall proceed to apply for researcher's pass or visa issued by the Department of Immigration Services in accordance with Kenya Citizenship and Immigration Act, 2011. The pass is issued to a person entering Kenya for purposes of research within Kenya for a period not exceeding twelve (12) months. However, such person must be affiliated to a local institution. The pass is required by NEMA together with letter of affiliation for processing of access permit.

5.1.5 Acquisition of Prior Informed Consent and Mutually Agreed Terms

After receipt of research licence, the applicant may/will establish contact with appropriate genetic resource provider through the public administration to commence the process of acquiring prior informed consent and mutually agreed terms.

The applicant may use the following general steps to acquire PIC and MAT:

- a. If the potential GR user is a foreigner, the applicant must identify a local collaborator who is a lead agency/designated national competent authority, research institution, academic institution, NGO, CBO or private person/institution. For the CBO and private sector, a letter of support in terms of capacity from lead agencies is required.
- b. Upon receipt of research licence and researchers' pass, the potential user must liaise with the local partner to visit NEMA for assistance and reference purposes.
- c. The applicant will then establish contact with the resource provider through NEMA and the public administration for purposes of seeking PIC and MAT.
- d. The potential GR user will then liaise with NEMA and local administration to call for a community meeting comprising relevant stakeholders to negotiate PIC and MAT.
- e. The Output of the meeting which will form part of the documentation to be submitted to NEMA should include the following:
 - Confirmed minutes of the meeting which must be duly signed.
 - Attendance list duly signed by the participants complete with their contact details.
 - Evidence of the information provided by the GR user to the community.
 - Any additional evidence e. g. photos, videos etc.
- f. At the meeting, the community will identify and authorize a person who will sign the PIC and MAT on their behalf.
- g. The potential GR user will incorporate the agreed concerns from the public meeting in the project proposal document.
- h. The potential GR user and the providers will complete and sign the PIC and MAT.
- i. The potential GR user will submit copies of the duly completed access permit application, PIC, a project proposal, MAT and minutes of the public meeting among other requirements to NEMA (see Appendix III for more information).

The consent from the GR providers should not be construed to mean permission to access GR. It should be based on truthful¹ information about the use that will be made of the GR. This information will be adequately revealed to the local community or any resource provider for clear understanding of the implication of use and the impacts on the environment.

5.2 Process For Acquiring Access Permit

The access procedure involves the following steps:-

5.2.1 Filing Access Permit Application

The first step is to fill an application form as set out in the First Schedule of the ABS Regulations 2006 and found on-line at www.nema.go.ke. Once the application form is duly filled and signed, the applicant is required to attach copies of the following:

- i. Evidence of payment of prescribed fee to NEMA
- ii. ID for Kenyans, passport for foreigners and PIN for corporate or organizations
- iii. Confirmed and duly signed minutes of meeting with the community on PIC
- iv. Attendance list in (iv) above duly signed by the participants complete with their contact details
- v. A duly executed PIC and MAT set out as a legally binding Memorandum of Understanding between the GR provider and the applicant
- vi. Research license from NACOSTI
- vii. MoU or equivalent, providing the frame-work for collaboration with a counterpart in Kenya
- viii. Project Proposal indicating; title, scope, objectives, methodologies, and expected outputs
- ix. Curriculum vitae of all personnel to be involved in the project, and

¹ It is an offence under EMCA, 1999 and the ABS Regulations to provide false or misleading information to the Authority/any of its officers. Article 69 (2) of the Constitution obliges every person to cooperate with state organs and other persons to protect and conserve the environment and use of natural resources.

- x. Environmental Impact Assessment Certificate, where applicable.

5.2.2 Formal Review of the Application

Upon receipt of the access permit application, NEMA carries out a formal examination of the application to ascertain that it meets all the formal requirements including the attachments. If the application does not meet formal requirements, the applicant will be notified to remedy the application within a specified period of time.

5.2.3 Publication and Notification of Application

If all the requirements have been met, NEMA publishes the application in the Kenya Gazette and in at least one newspaper with nationwide circulation or in such other manner as it may consider appropriate. This is to invite public comments on the application for the access permit and to encourage the public to participate in the management, protection and conservation of GRs.²

The publication specifies;

- a) The name and other particulars of the applicant,
- b) The activity to be undertaken for which the access permit is required, and
- c) The time within which representations or objections in respect of the proposed access permit may be made to NEMA.

5.2.4 Determination of Application

Upon expiry of the stipulated publication period, NEMA invites ABS Technical Committee (TC) comprising various key stakeholders to determine the application taking into consideration the comments from the public and other stakeholders. If TC is satisfied that the activity to be carried out will facilitate sustainable management and utilization of the

² Consistent with Article 69 (1) (d) and 69 (2) of the Constitution.

GRs for the benefit of the people of Kenya³, it will recommend to NEMA to issue an access permit.

5.2.5 Communication of the Decision on Application

The decision to grant or reject the application for access permit is communicated in writing to the applicant within sixty (60) days from the date of receipt of the application.

5.2.6 Conditions of Access Permit

The permit is not transferable. It is valid for a period of one year but may be renewed for a similar period.

5.2.7 Appeal

Any person aggrieved with the decision of NEMA may appeal to the National Environment Tribunal as provided for in section 11 (3) of the ABS Regulations, 2006.

³ See Article 69 (1) (h) of the Constitution.

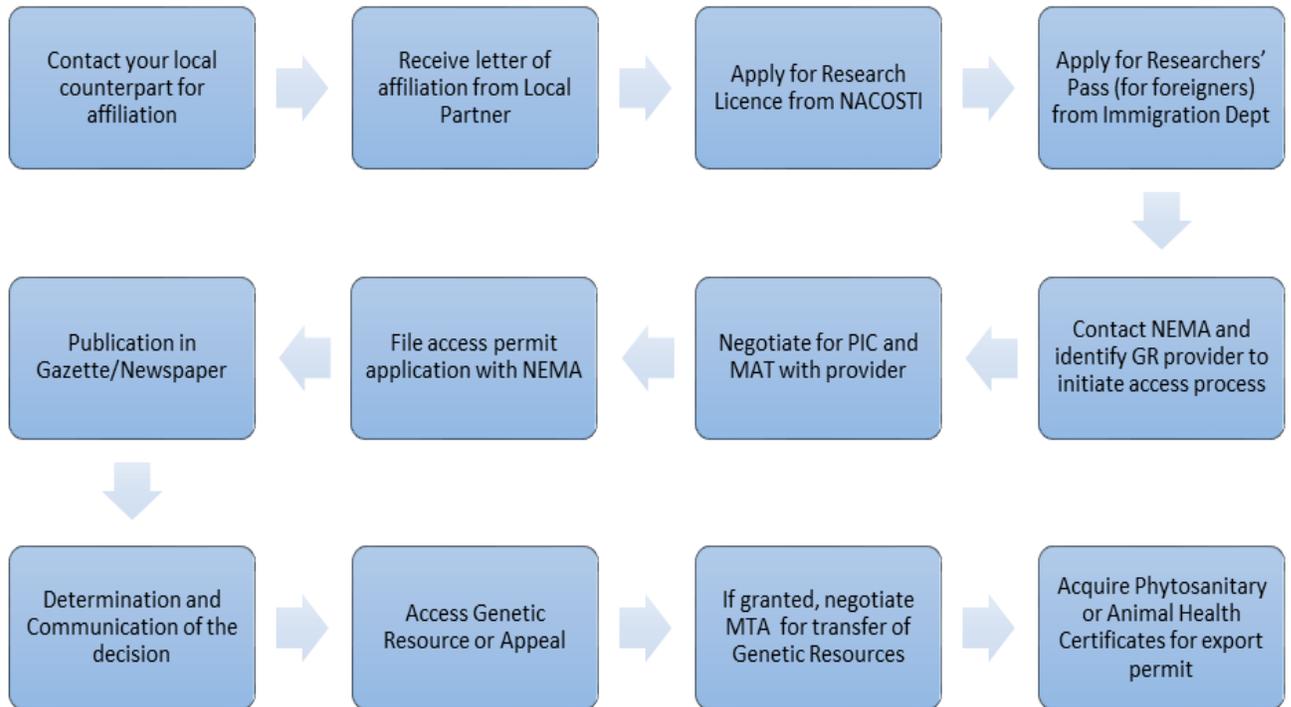


Figure 5.1: Flow Chart of Access Procedure in Kenya

5.3 Post Access

After access, a permit holder wishing to transfer GR outside Kenya is required to implement Material Transfer Agreement (MTA) terms and conditions (see sample in appendix IV) with the relevant lead agency.

5.3.1 Execution of Material Transfer Agreement

If the permit holder intends to transfer the resources, the following general steps may apply in negotiating for MTA:



- a) Engage the relevant lead agency in which the GR under consideration falls and initiate negotiation of terms of transfer of the GRs and/or associated traditional knowledge
- b) Negotiate and complete MTA (modelled in Appendix IV) customize it appropriately to suit the genetic materials under consideration
- c) Ensure the agreement is signed and dated by legally authorized persons in both contracting parties
- d) Submit a copy of the executed MTA to NEMA for further information.

Any person who receives materials under an MTA must ensure that his or her project team understands the requirement of the agreement, including the allowable scope of work for use of the genetic material received and restrictions on sharing the materials with those outside the projects. A party in breach of the conditions of an MTA is liable to legal proceedings.



Plate 5.2: Verification of Genetic Material

5.3.2 Application for Export Permit

Permit holders wishing to export genetic resources from Kenya must apply for and obtain an export permit from the relevant lead agency such as KWS by attaching either of the following documents:

- a) **Phyto-sanitary Certificate**

Plant GR designated for export must meet phyto-sanitary requirements of the importing country. The access permit holder must acquire phyto-sanitary certificate from KEPHIS prior to export in case of plant genetic resources.

b) Animal Health Certificate

Animal genetic resources designated for export must receive a health clearance certificate from the Department of Veterinary Services.

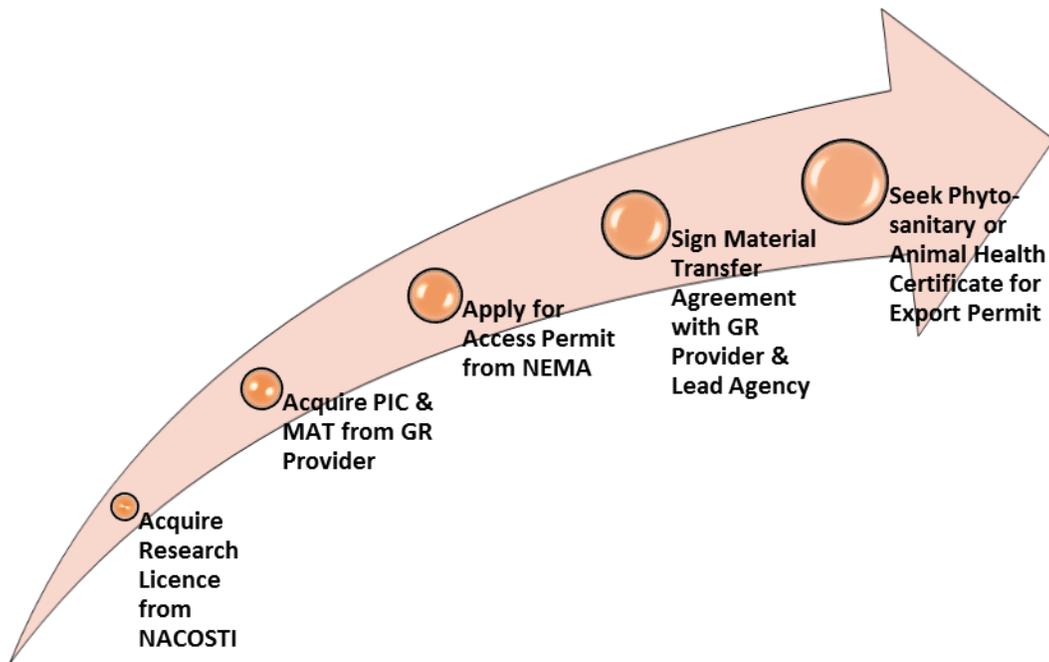


Figure 5.2: Processing of Acquired Genetic Resources for Export

5.4 Monitoring Compliance

There are various laws and regulations governing access and benefit sharing in the country which act as tools of compliance. Key among them is the ABS Regulations of 2006 developed under EMCA, 1999. It is important to note that violation of the access and benefit-sharing Regulations 2006, constitute offences under the Act, EMCA, 1999; and violation of Kenyan Constitution (Constitution of Kenya, 2010). Various Acts related to ABS are listed in Appendix V of the Toolkit. Violation of any of these Acts may result in fines, imprisonment and other consequences. Violation may also increase the transaction time needed to obtain a formal access permit by an applicant.

Lead agencies, designated national competent authorities, and providers of GR are responsible for observance of the law and enforcement at any of the stages of ABS. Therefore, it is essential not only to know the relevant policies, principles and laws, but also to have a practical understanding of the various tools and the required procedural steps necessary for full compliance.

The Government of Kenya has taken appropriate legislative and administrative measures to ensure that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by access and benefit-sharing legislation or regulatory requirements of the user party. It is expected that both provider and user of GR will adhere to their obligations and comply with conditions and requirements of all the agreements, licenses, permits and certificates. The provider and user of GR are required to implement PIC, MAT, Access Permit conditions and MTA to the letter. This is monitored by NEMA, relevant lead agencies and the local community.

5.4.1 *Compliance with Additional Responsibilities Imposed on Use of Access Permit*

(a) The permit holder in liaison with the counterpart should share with stake holders information on the state of duplicates and holotypes of all GR collected and deposited with the relevant lead agency in Kenya.

- (b) The permit holder should deposit with NEMA records of all intangible components of GR collected and deposited with the lead agency.
- (c) The permit holder is required to submit quarterly reports to NEMA on the status of research, including all discoveries made involving genetic resources and/or intangible components.
- (d) The permit holder will promptly inform NEMA of all discoveries made during the exercise of the right of access granted under the access permit.
- (e) The holder of an access permit will also regularly provide the following reports:
 - (i) A semi-annual status reports on the environmental impacts of any on-going collection of genetic resources or intangible components,
 - (ii) A final status report on the environmental impacts of collection of genetic resources and intangible components in the event that the collection is of a duration of three months or less, where applicable.

5.4.2 Suspension and Cancellation of Access permit

As provided for in the ABS regulations 16 (1, 2 and 3), The Authority may suspend, cancel or revoke any access permit issued under these Regulations where the holder thereof is in contravention of any of the conditions imposed on the access permit or those implied under these Regulations, or of the agreements concluded pursuant to its grant.

5.4.3 Compliance with Benefit Sharing Plan

The permit holder shall comply with the benefit sharing plan as outlined in Benefit Sharing Plan in this toolkit.

5.4.4 Compliance with Terms of Agreements and ABS Regulations

Any permitted GR and associated TK user shall:

- a. Use Collected Genetic Resources in a manner consistent with the terms and conditions specified in an applicable Agreement.
- b. Do not use Collected Genetic Resources, for purposes other than those specified in the Prior Informed Consent provisions of an applicable Agreement, unless first obtaining a separate Prior Informed Consent in writing for the other use of the Collected Genetic Resource.
- c. After acquiring Collected Genetic Resources pursuant to ABS Regulations, maintain records concerning the handling, storage and physical movement of the Collected Genetic Resources, and be prepared to share such records with the Providing Party upon the request of the Providing Party, within reasonable limitations.
- d. Ensure that the terms and conditions specified in an Agreement entered into with Kenyan Government or a Providing Party apply to (i) any successor in interest to their rights under the agreement, and (ii) to any party that obtains a sample of a Collected Genetic Resource from it, unless those parties have independently obtained from the Kenyan Government or the Providing Party the right to obtain such samples of the Collected Genetic Resources.
- e. Do not transfer samples of Collected Genetic Resources to third parties unless such transfer is consistent with the terms and conditions of an applicable Agreement.
- f. Do not accept samples of Collected Genetic Resources from a third party that is not able to provide evidence that it has obtained such samples in compliance with obligations of Prior Informed Consent and conditions governing use that are applicable to the sample.
- g. Include provisions in the Agreement that provide for effective and fair resolution of disputes regarding compliance with the terms and conditions in the Agreement, either by commitments to international arbitration consistent with the procedures

specified in the ABS Regulations or as otherwise agreeable to the Government of Kenya or Providing Party.

5.5 Trans-boundary Measures

In cases where the same genetic resources or TK are found *in situ* within Kenya and other neighbouring country such as Uganda or Tanzania, the Government will endeavour to cooperate with the neighbouring country and involve indigenous and local communities concerned, where applicable, with a view to implementing PIC, MAT and other ABS Agreements and the objectives of the Nagoya Protocol.

5.6 Internationally Recognized Certificate of Compliance

The access permit issued in accordance with ABS Regulations is submitted to the CBD Access and Benefit-Sharing Clearing House to constitute an Internationally Recognized Certificate of Compliance. The Certificate of Compliance serves as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the Kenyan access and benefit-sharing regulatory requirements.

Non-confidential internationally recognized certificate of compliance contain at least the following information:

- (a) Issuing authority;
- (b) Date of issuance;
- (c) The provider;
- (d) Unique identifier of the certificate;
- (e) The person or entity to whom prior informed consent was granted;
- (f) Subject-matter or genetic resources covered by the certificate;
- (g) Confirmation that mutually agreed terms were established;
- (h) Confirmation that prior informed consent was obtained; and
- (i) Commercial and/or non-commercial use.

5.7 Checkpoints and Monitoring Utilization of Genetic Resources

To support compliance, certain lead agencies have been designated to play the role of watchdogs. This is important to enable users enhance accountability and transparency about the utilization of accessed genetic resources through various measures. Checkpoints are institutions and organizations charged with monitoring compliance with the relevant agreements and application of ABS tools by both user and provider.

For instance, the Government has designated NEMA, resource providers, lead agencies, local community and other resource regulators as checkpoints to monitor use of GR at various stages of development. Checkpoints collect or receive, relevant information related to:

- a. prior informed consent,
- b. the source of the genetic resource,
- c. the establishment of mutually agreed terms, and/or
- d. the utilization of genetic resources.

In addition, NEMA may require users of genetic resources to provide information and data specified in the Regulations.



Plate 5.3: Customs & Excise Duty Monitoring of Movement of GR at Customs

Checkpoints are required to be effective and able to perform functions relevant to implementation of the conditions set forth in ABS agreements. They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.

In Kenya, NEMA, NACOSTI and the relevant lead agency acts as the checkpoints on conditions and obligations of the user as indicated in the letter of intent, letter of affiliation, PIC, MAT, MTA etc. The Kenya Industrial Property Institute (KIPI) acts as ABS checkpoint during filing and examination of patent applications by ensuring that when GR users file patent application on novel innovations involving genetic resources or traditional knowledge disclose the source. Department of Immigration monitors the conditions imposed visa and other documents for movement. NEMA and relevant lead agencies monitors the research progress through quarterly reports. The local community is responsible for developing and overseeing the observance of bio-cultural community protocols during access the GR and TK by the user group and oversight collection of materials for environmental sustainability. A list of likely checkpoints is provided below in table 2:

Table 5.1: List of selected Checkpoints in Kenya

S.NO.	ABS CHECKPOINT	MONITORING ROLE
1.	National Environment Management Authority (NEMA)	As ABS Focal Point. During post-access requirements such as research progress reports, access permit renewal etc.
2.	Kenya Wildlife Service (KWS)	Obligations of user and provider in MAT, MTA and wildlife export permit
3.	Kenya Forest Service (KFS)	Obligations of user and provider in MAT and forest product permit
4.	Kenya Plant Health Inspectorate Service (KEPHIS)	Conditions attached to Phyto-sanitary Certificate
5.	Kenya Agricultural Research Institute (KARI) through the National Gene bank	Obligations of user in Access Agreement or MOU for <i>ex-situ</i> plant genetic resources accessed under the ITPGRFA Protocols
6.	National Museums of Kenya (NMK)	Obligations of user and provider in MAT and collection export permit
7.	Kenya Medical Research Institute (KEMRI)	Obligations of user and provider of human GRs and related biodiversity
8.	Department of Veterinary Services	Conditions imposed on Animal Health Certificate
9.	Public Universities & Other Research Institutes	Conditions and requirements of the user as put forth in the Letter of Affiliation and Collaborative Research Agreements or MOUs
10.	Department of Immigration	Researcher Pass conditions
11.	National Commission for Science, Technology & Innovation (NACOSTI)	Scope and conditions attached to the Research Licence
12.	Kenya Industrial Property Institute (KIPI)	Disclosure of source of GR and TK in patent applications or enclosure of MAT
13.	County Governments, Local Communities, NGOs & Private GR resources managers	To monitor obligations of the GR user as per PIC and MAT conditions
14.	Kenya Bureau of Standards (KEBS)	To monitor source of origin of raw material for products during certification
15.	Customs & Excise Duty	To monitor movement of material and goods across boundaries



16.	Development Partners	To assist monitoring at various stages
17.	Local Community	To monitor compliance with community cultural protocols

5.8 Access and Benefit Sharing Technical Committee

NEMA established Access and Benefit Sharing Technical Committee (ABS Technical committee) whose composition is multi-stakeholder in nature. This approach ensures that there is further stakeholder consultation. It also ensures that the decisions made are fairly objective by providing a broader range of expertise, perspectives and opinions on the proposed project.

5.8.1 Functions ABS TC

- a) Determination of the access permit applications to ensure that they are in the national interest;
- b) Monitoring of compliance with agreements and permit conditions;
- c) Assisting in the implementation of the ABS Regulations.

5.8.2 Members of ABS Technical Committee

- i. Ministry of Environment and Mineral Resources (MEMR)
- ii. National Environment Management Authority (NEMA)
- iii. National Commission for Science, Technology and Innovation (NACOSTI)
- iv. Kenya Industrial Property Institute (KIPI)
- v. Kenya Wildlife Service (KWS)
- vi. Kenya Forest Service (KFS)
- vii. Kenya Plant Health Inspectorate Service (KEPHIS)
- viii. Kenya Agricultural and Livestock Research Organization (KALRO)
- ix. National Museums of Kenya (NMK)
- x. Kenya Medical Research Institute (KEMRI)
- xi. Indigenous Information Network (IIN)
- xii. Directorate of immigration





xiii. Department of veterinary services

Representatives of other institutions may be co-opted when required for their additional expertise. NEMA provides the secretariat and technical expertise while the various lead agencies provide technical expertise to the ABS Technical Committee. This approach makes best use of limited human and institutional resources.



6 APPENDICES

APPENDIX I : SAMPLE PRIOR INFORMED CONSENT (PIC) FORM

PART A: Details of the Resource User and Local Partners/Affiliates

*This part shall be filled by the person seeking to access the GR and/or associated knowledge.
The person can be either an individual, corporate or organization*

Resource User

1. Individual

- a. Name.....
- b. ID No. /Passport No.....PIN No/ Visa No.....
- c. Country of Origin
.....Nationality.....
- d. Valid Work permit No/Research Permit (If applicable).....
- e. Telephone No: Include area
codes.....
- f. Applicants home Organization:
 - (i) Postal address:
 - (ii) Physical Address.....
 - (iii) Fax.....
 - (iv) E-
mail.....Website.....
- g. Official contact person (in case of legal entity).....

2. Corporate / Other Organizations

- a. Name of Corporate/Organization.....
 - i. Postal address.....
 - ii. Physical Address.....
 - iii. Fax.....
 - iv. E-mail.....Website.....



- b. Name of person completing the form.....
 - (i) ID No. /Passport No.....PIN No. / Visa No.....
 - (ii) Valid Work permit No..... (If applicable)
- c. Telephone No: Include area codes.....
- d. Person to contact (in *case of legal matters*).....

3. Local Partner/Affiliates (if applicable)

- a. Name.....
- b. Postal address.....
- c. Physical Address.....
- d. ID No. /Passport No/PIN No.....
- e. Tel No.....
- f. Fax. No.....
- g. E-mail.....
- h. **Official contact person (Chief executive officer of affiliating institution):**
 - i. Name.....
 - ii. Title.....

4. Project type

a. **Proposed Project** (Indicate by placing X in the box provided)

- (i) Educational research
- (ii) Commercial Use
- (iii) Industrial application
- (iv) Bio - prospecting
- (v) Conservation
- (vi) Other (specify).....

b. Genetic resource(s) to be accessed





- (i) Plants
- (ii) Animals
- (iii) Vertebrates
- (iv) Invertebrates'
- (v) Micro-organisms

(vi) Scientific nameCommon name:
..... Local name (if known).....

- (vii) **Status of conservation**
- - Abundant
 - Endemic
 - Rare
 - Threatened
 - Endangered





c. **Details about Genetic Resource to be accessed** (Indicate by placing X in the box provided)

Type (whole or part)	Unit of measurement	Quantity	Frequency of collection

d. **Methodologies of collection** (briefly describe how genetic material above will be collected from the organism).

.....
...

e. **Sites/habitat in which collection will be undertaken** (County, locality, GPS where possible)

.....

f. **Attach documented bio-cultural protocols**

.....

g. **Duration of material collection activity** (*Days, Months, Years*)

- How long will analysis take

h. **Location/ where the analysis and development will take place**

i. **Further details required in case of applied research**

- i. Are you aware of any product made of the material you are proposing to access? Yes / No...
- ii. Are you aware of any specific uses of the material by the local community where it is found? Yes/ No
- iii. Are you aware of any current industrial application of the material Yes/ No

j. **Role of local community in the project** (provide details on how the community where material is found will participate in the project)





Potential Impacts

Describe briefly the potential impacts of accessing the genetic resource(s) on the environment and the socio-economics of the provider community.

- (i) Impacts on the environment
 -
- (ii) Socio-economic impacts
 - Proposed mitigation measures
 -

k. Third Party Involvement

Indicate potential involvement of third parties

- i.
- ii.
- iii.

5. Benefit Sharing Arrangements

The benefits derived from accessing genetic resource will be shared in accordance with the Mutually Agreed Terms (MAT) annexed hereto.

6. Communicating project implementation

Provide the ways in which an audit of accrued benefits agreed under MAT will be ensured during and after the project period.

7. Project Budget

Indicate the overall project budget.....

8. Additional Information:





Provide any additional information the provider should know in order to make an informed decision of permitting your access to the genetic resource(s).

.....
.....

PART B (The Persons /Community to be involved)

Details of Genetic Resource Provider

This part shall be filled by the person providing Genetic Resource (GR Provider). The person can either be an individual, corporate, organization or community.

1. Community /Corporate or organization/ Individual

- a) Name
- b) Address.....
- c) Physical Address.....
- d) ID No/Passport No.....
- e) PIN No.....
- f) Tel. No.....Fax No.....
- g) E-mail

Notes on documents to enclose

- a) For community attach authority to act on behalf of the community duly executed by the community's representatives and or a resolution to that effect in case of the more organized communities e.g. duly signed minutes.
- b) For Corporate/organization above attach authority/resolution to act on behalf of the organization

DECLARATION





Read carefully the information provided in Part A before appending your signature below

I/We a resident
of.....;(county; sub-county;
location) and of P.O Box..... County hereby
declare that:

1. I /we understand the scope, aims, and purposes of this project and the activities that are involved and the expected duration and manner of my/our participation.
2. I/we have received a description of reasonable foreseeable risks associated with this project; I/we have had them explained to me/us, and understand them.
3. I/we have received a description of potential benefits that may accrue from this project and understand how they will be shared
4. I/we understand that the confidentiality of all data, records and IP rights associated with my/our participation in this project must be within the extent of the law.
5. I/we understand my/our obligations as citizen to the state and county governments as pertains to access to and benefit-sharing from genetic resources and associated TK in Kenya.
6. I/we confirm that no coercion or inducements of any kind was used in seeking my participation in this project.
7. I/we understand that if my/our rights as a genetic resource(s) provider are infringed upon, I/we have the right to be given the opportunity to discuss redress with the above named user, failure hitherto I/we have the right to seek redress at the Environment and Land Court of Kenya.
8. I/we understand that any outputs from this project will be associated with me/us.





9. I/We understand that I/we have a duty to cooperate with state organs and other persons to protect and conserve the environment and ensure ecologically sustainable development and use of natural resources.

10. I/We hereby consent to the access of (name (s) of biological resources and/ or state the associated knowledge) by (name of the person/institution seeking to access) for the uses stated in Part A, 4 (e).

Signatures

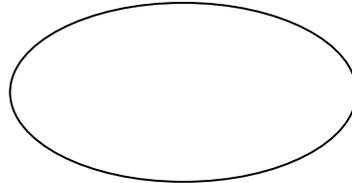
Genetic Resource Material Provider

Name.....

ID NO-/Passport No...../PIN. No.....

Date.....Signature.....

(Seal/stamp)



In the presence of (witness)

Name.....

Official rubber stamp

ID No/Passport No..... PIN. No.....

Date.....Signature.....

Genetic Resource User

Name.....





ID NO. /Passport No.....

PIN. No

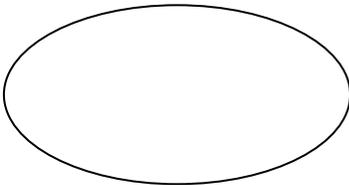
Consent

Do not Consent

to the contents of

this Prior Informed Consent.

Date.....Signature..... (Seal/stamp)



In the presence of (witness)

Name.....

ID No. /Passport No.

Date.....Signature.....

NB: Where the provider is a Private GR owner the relevant lead agency must witness.





APPENDIX II: SAMPLE MUTUALLY AGREED TERMS FORMAT

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding is entered **BETWEEN**

.....

(Insert the name of the provider) AND (Insert the name of user)

IN RELATION TO *(Insert appropriate title of the project)*

Whereas the sovereign rights over biodiversity are vested in the State; and

Noting that Kenyan Government has put in place various legislative measures for sustainable utilization and conservation of biodiversity such as; the Constitution of Kenya (2010), Environmental Management Co-ordination Act (EMCA) 1999, the Wildlife (conservation and Management) Act, Amendment 1989, the Forest Act of 2005, Industrial Property Act, 2001, Plants and Seed Varieties Act, Cap 326, Kenya Agriculture Research Act, 2012, the Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations 2006;

NOW THEREFORE the parties agrees as follows:

1: PARTIES TO THE AGREEMENT

These Mutually Agreed Terms (MAT) hereinafter referred to as 'the agreement' is entered into at..... (Insert location) on this day..... of _____ [insert year]:
BETWEEN, P. O Box, Physical Address.....,
Tel., Fax:, E-mail:..... Here in-after referred to as **Provider**, AND, P. O Box





....., Physical Address.....,
Tel....., Fax:, E-
mail:.....herein-after referred to as **User /recipient**.

2: USE OF TERMS

In this **Agreement**, the expressions set out below are defined as indicated in the glossary of this toolkit.

3: SCOPE AND OBJECTIVES OF THE AGREEMENT

3.1. Scope

This Agreement shall apply to access and benefit sharing of genetic resources for both non-commercial and commercial uses within the scope of the Constitution of Kenya, 2010 and the laws of Kenya.

3.2 The objectives of this Agreement

To facilitate:

- a. Access to genetic resources including derivatives and associated TK,
- b. Sustainable utilization of the genetic resources including derivatives,
- c. Transfer of genetic resources including derivatives to third parties, and
- d. Sharing the benefits resulting from the utilization of genetic resources including derivatives.

4: STATEMENT OF WORK (PROJECT SUMMARY)

4.1 The user shall attach a (1-2 page) description of the project that includes elements in Annex 1 of this Agreement.

4.2 The Genetic resource(s) shall be accessed from (*insert exact locality where the resource is to be accessed including the GPS coordinates, L.R. No., e.t.c*)





4.3 Title and Objectives of the Project shall be

5: OBLIGATIONS OF PARTIES

5.1. Obligations of the Provider

5.1.1 To allow the user to access the genetic resource and/or associated traditional knowledge – (*specify the nature of material or species and the part(s) of the species to be accessed*) relating to:

5.1.2 To conserve the genetic resources and preserve any associated traditional knowledge

5.1.3 To collaborate with a relevant lead agency/ies in providing the genetic resource

5.1.4 To facilitate the user(s), designated and competent authorities with information and data pertinent to the utilization of the genetic resources

5.1.5 To meet minor costs incidental to the access, including organizing for community meetings and reporting

5.1.6 To adhere to terms and conditions of this Agreement

5.1.7 To renegotiate for PIC, and MAT (where applicable) during variation of the access permit,

5.1.8 Shall disclose and share information on:

- a) Any known use of the accessed material.
- b) Any potential use.

5.2. Obligations of the User

5.2.1. Shall ensure that they obtain an access permit from the designated authority prior to accessing genetic resource(s)



5.2.2 Shall collaborate with a relevant lead agency/ies in accessing the genetic resource

5.2.3 Shall facilitate the provider(s), designated and competent authorities with information and data pertinent and resulting from the utilization of the genetic resources including derivatives

5.2.4 Shall meet all costs incidental to the access, including technology transfer and reporting

5.2.5 Shall use the GR and/or associated TK as specified in PIC consent and MAT.

5.2.6 Shall renegotiate the PIC, and MAT (where applicable) and apply for a variation of the access permit, if s/he intends to vary the use of the GR and or its derivatives in the initial PIC and MAT.

5.2.7 Shall disclose and share information on:

- a) Any known use of the accessed material.
- b) Any potential use.

6: CONFIDENTIALITY

6.1 All parties hereby undertake to treat as confidential any data and information generated by either party during and after access and declares in writing to be confidential and which is not otherwise known or available to the public (hereinafter referred to as 'Confidential Data')The **Designated National Authority** and/or **Competent Authority** shall give the user thirty (30) days written notice of its intention to publish data and information provided by the user to a third party in public interest or safety.

6.2 Confidential TK shall not be disclosed without PIC from the original holder.

6.3 TK, information and data disclosed and or generated during access to the GR



shall not be disclosed to third parties without consent of the provider⁴.

7: REPORTING

Parties agree that;

7.1. The User shall submit a written quarterly report to **the Competent Authority** and the **Designated National Authority** with effect from the date of issuance of access permit.

7.2. The user shall submit a written annual report to the provider from the date of issuance of access permit. Where the provider is a local or indigenous community, a summary of the report shall be adapted to a non-scientific audience and translated into Kiswahili or local language by the **Competent Authority** using the existing communication mechanism at the cost of the user.

8: BENEFIT SHARING

The **Designated National Authority, Competent Authority, Provider, User and Local Community** shall work together to share fairly and equitably the benefits arising out of the genetic resource and/or associated traditional knowledge as spelt out in this **Agreement** and shall have a clear benefit sharing plan indicating both monetary and non-monetary benefits as outlined in Annex 2 of this Agreement.

9: OWNERSHIP OF GENETIC RESOURCES AND ASSOCIATED KNOWLEDGE

9.1 The Government of Kenya shall retain ownership of, and title to the genetic resource accessed by the user on behalf of Kenyan citizens.

9.2 The Government will ensure that special arrangements are made to transmit equitable benefits to the provider including the local community.

10: INTELLECTUAL PROPERTY RIGHTS

⁴ NB: Parties may develop separate confidential agreement/s binding themselves to keep in confidence certain information that they consider secret.



10.1. The user shall not file or obtain whether in the country of the user, Kenya or elsewhere any intellectual property rights over any accessed genetic resource under this Agreement including any properties, derivatives or processes including those that may utilize the knowledge of local communities regarding any product or process, even if the process has been modified to a more sophisticated level of commercialization for extracting, isolating or synthesizing the chemical extracted from the genetic resource without prior agreement with the provider.

10.2. In the event that the intellectual property application must be filed urgently and may not have adequate time to notify the provider, the user shall notify the provider and DNA of such filing within fourteen days.

11: TRANSFER TO THIRD PARTIES

The user shall not transfer genetic resources or any component thereof to third parties without first having explicit written consent from provider.

12: TERMINATION OF AGREEMENT

This agreement shall be terminated as follows:

12.1 If the user is in the process of bankruptcy, the lead agency and the provider can immediately terminate the agreement.

12.2 If one of the parties repeatedly fails to fulfill or repeatedly violates its obligations under this agreement, PIC and/or MAT then the aggrieved party may terminate the agreement upon 30 days notice given in writing to the other party (ies).

12.3 Termination of this agreement, except in the case of bankruptcy, will be done through mutual agreement by all parties.

12.4 The termination of this agreement shall not affect the rights and obligations that were due to accrue to any party (ies) prior to the effective date of termination.

12.5 Starting with the day of termination of this Agreement, the user shall stop using the genetic resources. However, the user will continue to use co-owned product upon payment of royalties agreed upon by all parties.

13: HANDLING OF THE GENETIC RESOURCE AFTER TERMINATION

13.1. Upon completion of the project or termination thereof, the genetic resource shall be **returned** to the provider at the expense of the user or destroyed as may be determined by the DNA and lead agency.

14: FORCE MAJEURE

14.1 Neither party (ies) shall be liable to the other party (ies) for any delay or non-conformance of its obligations under this Agreement arising from any clause beyond its reasonable control, including, but not limited to, any of the following: Act of God, decree, war, fire, drought, explosion, civil commotion or industrial disputes of a third party or impossibility of obtaining gas or electricity or materials.

14.2. The affected party (ies) must promptly notify the other party (ies) in writing, but in no circumstances no later than 14 days, of the cause and likely duration of the cause.

14.3. Such notice having been given, the performance of the affected party's obligations, to the extent affected by the cause, shall be suspended during the period the cause persists.

14.4. Without prejudice to the above, the affected party (ies) must take all reasonable measures to minimize the impact of any force majeure on the performance of its obligations under the Agreement and to ensure, as soon as practicable, the resumption of normal performance of the obligations affected by the force majeure.

15: Applicable Laws

15.1 This agreement is governed by and shall be construed in accordance with the laws of Kenya.



16: DISPUTE RESOLUTION

16.1. Any dispute, difference or question arising out of or in connection with this agreement, including any question regarding its existence, validity or termination shall, to the extent possible, be resolved by negotiation, mediation and/or conciliation.

16.2. In the event that the dispute remains unresolved for more than three (3) months from the date when the dispute is first notified in writing by either party to the other party, the dispute shall be referred to and finally settled through arbitration in accordance with the Arbitration Act No. 4 of 1995 of laws of Kenya as amended from time to time or it shall be submitted to an arbitration body in accordance with the procedure laid down in part 1 of Annex II of the Convention on Biological Diversity.

16.3. If either of the parties fails to comply with the award of the arbitral tribunal, the aggrieved party(ies) may, in accordance with paragraph 16(d) (iv) of the Annex to Section A of Decision VI/24 of the 6th Conference of the Parties of the Convention on Biological Diversity, UNEP/CBD/COP/6/20, the Hague, 7-19 April 2002, ask the Government of Republic of Kenya or the Government of Netherlands to enforce the award given by the arbitral tribunal.

17: NOTICE

17.1. Any notice or other document to be served under this Agreement must be delivered by hand or sent by registered mail or by international courier service to be served at the addresses below:

The..... the **Provider**, P. O Box, Physical Address....., Tel., Fax:, E-mail:.....

or





The.....the **User**, P. O Box, Physical
Address....., Tel....., Fax:
....., E-mail:.....

Copied to:

- a) Competent Authority (*Insert the name of the Institution and the address*)
- and
- b) Designated National Authority (*Insert the name of the Institution and the address*)

17.2. All notices or documents shall be deemed to have been served at the date and time of delivery of the said notices or documents to the recipient party.

18: ENTIRE AGREEMENT

18.1 The provisions of this agreement and the contents of Prior Informed Consent constitute the entire agreement between the parties and the parties do not make any representations or warranties except those contained in this agreement and Prior Informed Consent. The agreement shall only be extended or amended by consent in writing and signed by authorized representatives of the parties of this Agreement.

19: NO ASSIGNMENT

19.1 This agreement is specific to the parties and none of the rights or the obligations under this Agreement may be assigned or transferred without the prior informed consent of the other party (ies).

20: NO PARTNERSHIP IN LAW

20.1. Nothing contained in this Agreement shall constitute a partnership in law between the Competent Authority, Provider and User or constitute either of the Agent of the other.





21: MONITORING & EVALUATION

21.1. The parties to this agreement shall put in place and implement appropriate measures for monitoring and evaluation of terms of this Agreement.

22: DISTRIBUTION OF COPIES OF AGREEMENT

22.1 Each of the parties to this Agreement shall receive and keep a copy bearing original signatures. In addition one counterpart of the Agreement shall be submitted to DNA at the time of applying for an access permit.

22.2 The language of this Agreement shall be English. There shall be translation of whole or in part into Kiswahili where necessary.

IN WITNESS WHEREOF the parties hereto, or their duly authorized representatives, have hereunto subscribed their hands and seals on the date and year mentioned above.

Executed as an Agreement

SIGNED on behalf of the

1. PROVIDER

(Insert the name of the provider)

By *(insert name of signatory)*

(Insert signatory position)

DATED

SIGNED on behalf of the

2. Witnessed by

(insert name of signatory)

(Insert signatory position)

3. USER





(Insert the name of the user).....

By (insert name of signatory)

(Insert signatory position)

DATE

4. Witnessed by

(insert name of signatory)

(Insert signatory position)

5. COMPETENT AUTHORITY

(Insert name of the institution)By..

(insert name of signatory)

(Insert signatory position)

DATED

SIGNED on behalf of the





APPENDIX III: SAMPLE MATERIAL TRANSFER AGREEMENT FOR ABS IN KENYA

Article: 1.0 Preamble

Whereas the sovereign rights over biodiversity are vested in the State;

Aware of the letter and the spirit of the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the 1992 Convention on Biological Diversity (CBD), Nagoya Protocol (2010), the 2004 International Treaty on Plant Genetic Resources for Food and Agriculture, Biological and Toxins Weapon Convention (BTWC) 1972 UN resolution 1540 (2004),

Recognizing that Kenyan Government has put in place various legislative measures for sustainable utilization and conservation of biodiversity such as; the Constitution of Kenya (2010), Environmental Management Co-ordination Act (EMCA) 1999, the Wildlife (conservation and Management) Act, Amendment 1989, the Forest Act of 2005, Industrial Property Act, 2001, Plants and Seed Varieties Act, Cap 326, Kenya Agriculture Research Act, 2012, the Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations 2006.

Noting the diversity, varied origins and inherent value of Kenya's genetic resources and their contribution to environmental health and socio-economic development.

Acknowledging: The rights of local communities to associated traditional knowledge on biological resources and its contribution to science, technology and innovation:

The parties hereby agree as follows:

Article 2.0 –Parties to the Agreement

2.1 This Material Transfer Agreement hereinafter referred to as the agreement is the official document for transfer of biological/genetic materials for Kenya.





The party(ies) to the agreement shall be recognised legal entities.

Private resource owners, international research organizations and nongovernmental organizations shall become party through relevant national agencies.

2.2 This agreement is between;

Provider(insert legal contacts of providing institution, names of authorized officers)

And

Recipient.....(insert legal contacts of receiving institution, names of authorized officers)

Article 3.0 Terms and Conditions of this Agreement

3.1The purpose and objectives: State the purpose whether: Academic, Research or commercial, taxonomy, collection, and expected outputs; include the title of the project and the abstract

.....

3.1.1 Objectives

.....
.....

Indicate type of material, source and GPS points

.....
.....

3.1.2 Provide documentary evidence of the following (Attach as annex):

- a) Deposition of duplicate specimen in designated repository center
- b) PIC and MAT

3.1.3 Provide associated traditional knowledge and source (if any)





.....
.....

4.0 Rights and obligations of providers and recipients

- a) Both the provider and the recipient shall notify the NEMA and any other relevant lead agency on the MTA implementation, material transfer to Third party, any discoveries and further use of the material through reports
- b) TK, information and data disclosed and or generated during access to the GR shall not be disclosed to third parties without consent of the provider.
- c) Confidential or proprietary GR information shall not be disclosed unless the information is in the public domain or is disclosed in public interest.

4.1. Rights and obligations of the provider

- i. The provider retains ownership of the genetic material including any material contained or incorporated in modifications.
- ii. The provider may repatriate genetic resources held by recipient with adequate prior written notice.
- iii. The provider also retains rights to any intellectual property it owns in genetic resource.
- iv. The provider retains the right to access, audit and monitor the use and application of the genetic material provided under this MTA.
- v. No rights under any intellectual property of Kenya or rights in any other material or confidential information provided by the Kenyan to the recipient under this agreement is granted or implied as a result of providing this material to the recipient, other than as expressly set forth herein.

4.2. Rights and obligations of the recipient

- i. The Recipient shall use the genetic resource(s) for the purpose stated in this agreement only



- ii. The Recipient is responsible for ensuring that all permits required for the movement of the material are obtained and that sufficient proof of such permits is provided to the provider whenever required to provide such proof.
- iii. In no circumstances shall the recipient collect materials in such a way that adversely affects the environment or in any way alter the genetic diversity of the source material
- iv. No commercialization shall take place without notice and a negotiated agreement with the provider.
- v. In the event of commercialization whether by the recipient, its servants and or agent or any party acting under it regardless of whether there was an act or omission on the part of the recipient resulting in the use and commercialisation of the GR without re-negotiation for the commercial license agreement the recipient will pay 50% of the gross income arising from the GR. In any case the provider shall become the duly recognised supplier of the genetic resource.
- vi. The Kenya Government shall have unrestricted access to the technologies and processes developed from the access and use of the GR.
- vii. In the event of commercialisation, the recipient and provider are enjoined in ownership of patents of inventions arising from utilization of genetic resources accessed as agreed.
- viii. The GR obtained under this agreement shall only be transferred by the recipient to a third party with prior written authorization from the provider and MTA between the recipient and the third party.
- ix. The recipient shall indemnify and keep provider indemnified from any claim, action, and damage or cost deriving from or in connection with the recipient's use of the GR.
- x. The recipient may file patent application(s) claiming rights over its

inventions made by recipient through the use of **GR** or modifications and in the event of technology transfer to third party or commercialization, the recipient shall negotiate with the provider prior to such use.

Article 5: Repatriation of Genetic Resources from Foreign Depositories

5.1 Due to national interests such as food or environmental security, the Government of Kenya may require the return of the remaining GR as required by the circumstances and recipient shall return such GR, to such institution as may be designated by **NEMA** without any condition.

5.2 The recipient shall use the genetic resource and/or associated traditional knowledge for the purpose(s) contained in this agreement and/or continue to keep the genetic resource in safe custody in accordance with standard procedures and practice.

Article 6: Termination of Agreement

6.1 This agreement is binding throughout the existence of the accessed GR.

6.2 On termination of this agreement, the recipient shall destroy (unless requested by provider to return the said remaining material) and shall provide proof immediately to the provider

6.3 Any procedurally duplicated GR/biological material shall survive the lifetime of this agreement and should be freely accessible to the Kenya government and the provider upon request.

Article: 7.0 Warranty

a) The **Provider** makes no warranties as to the safety of or title to the **GR material**, nor as to the accuracy or correctness of any information provided with the **Material**. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the **Material** being furnished.

b) The phytosanitary condition of the **Material** is warranted only as described in any attached phytosanitary certificate. The **Recipient** assumes full responsibility for

complying with the recipient nation's quarantine regulations and rules as to import or release of **genetic material**.

Article 8: Applicable Laws

The applicable law shall be the domesticating national laws of Kenya, the relevant provisions of the Nagoya protocol, and, when necessary for interpretation, the decisions of the NEMA.

Article 9: Dispute Resolution

Any dispute arising from **this Agreement** shall be resolved in the following manner:

- a) Amicable dispute settlement: The parties shall attempt in good faith to resolve the dispute by negotiation.
- b) Mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed.
- c) Arbitration: If the dispute has not been settled by negotiation or mediation, any party may submit the dispute for arbitration under the Arbitration Act No. 4 of 1995 of laws of Kenya and in accordance with the procedure laid down in part 1 of Annex II of the Convention on Biological Diversity.

Article 10: Force majeure

10.1 Neither party(ies) shall be liable to the other party(ies) for any delay or non-conformance of its obligations under this **Agreement** arising from any clause beyond its reasonable control, including, but not limited to, any of the following: government Act, war, fire, drought, explosion, civil commotion or industrial disputes of a third party or impossibility of obtaining gas or electricity or materials.

10.2 The affected party(ies) must promptly notify the other party(ies) in writing, but in no circumstances no later than fourteen (30) days, of the cause and likely duration of the cause.

10.3 Such notice having been given, the performance of the affected party's obligations, to the extent affected by the cause, shall be suspended during the period the cause persists.

10.4 Without prejudice to the above, the affected party(ies) must take all reasonable measures to minimize the impact of any force majeure on the performance of its obligations under the **Agreement** and to ensure, as soon as practicable, the resumption of normal performance of the obligations affected by the force majeure.

Article 11: Notices

Any notice or other document to be served under this **Agreement** must be delivered by hand or sent by registered mail or by international courier service to be served at the addresses below:

Designated National Authority

Insert the name of the Institution and the address

Competent Authority

Insert the name of the Institution and the address

Provider

*Insert the name of the **Provider(s)** and the address*

Recipient

Insert the name of the Institution and the address

All notices or documents shall be deemed to have been served at the date and time of delivery of the said notices or documents to the recipient party.

Signature/Acceptance

For provider

Name and Signature of Head of institution-----





Name and signature of Authorizing officer:-----

For recipient:

Name and Signature of authorized official-----

Name and signature of principal investigator-----

Witnessed by-----





**APPENDIX IV - IMPORTANT POLICIES, CONVENTIONS, LAWS AND REGULATIONS RELEVANT TO ABS
IN KENYA**

Serial Num	Policies, Laws and Regulations	Content	Analysis	Responsible Lead Agency
A. INTERNATIONAL TREATIES & PROTOCOLS				
1	The Convention on Biodiversity-CBD	Article 15 (Access to GR-States have the sovereign rights over their natural resources.) of the CBD, and also Article 8 (In-situ conservation) 8j (Applies to traditional knowledge associated with genetic resources in the scope of the CBD and to the equitable sharing of benefits arising from the utilization of such knowledge), Article 9 (Ex-situ conservation) on complimentary measures for biodiversity conservation, Article 16 (Access to and transfer of technology), Article 17 (Exchange of information), Article 18 (Technical and Scientific cooperation),	The CBD recognizes the sovereign rights of states over their natural resources, including biodiversity and the duty of the state to undertake legislative, policy and administrative actions for fair and equitable sharing of benefits of research and development arising from use of their resources and in addition, cooperate with other parties on the same.	CBD National focal institutions, Scientific authorities and the lead Agencies



		Article 19 (Handling biotechnology and distribution of its benefits).		
2	The Nagoya Protocol on ABS	<p>Article 1 on fair and equitable sharing of benefits arising from the utilization of Genetic resources, including by appropriate access to GR and by appropriate transfer of relevant technologies.</p> <p>Article 2; some terms in the convention</p> <p>Article 3, on scope; GR sensu CBD, TK sensu CBD</p> <p>Article 6, on Access</p> <p>Article 8, on access of GR for research, particularly in accommodating change of intent</p> <p>Article 5, 9, 10 on Benefit-Sharing</p> <p>Article 13 on National focal points and competent national authorities (Kenya as a party shall designate the National focal point-to provide information on ABS. And designate competent national authorities.</p> <p>Article 15, 16, 17, 18 on taking measures to</p>	<p>ABS is inseparably linked to appropriate access to genetic resources, the transfer of relevant technologies, information exchange, and scientific co-operation. Also to fair and equitable sharing of benefits arising from the use.</p> <p>The process for domesticating the Nagoya Protocol to include issues of TK etc is underway, following its ratification in Kenya, May 2014.</p>	<p>NEMA and the designated national competent authorities on ABS, Lead agencies, National security and Judiciary for breach of the law.</p>



		ensure compliance		
3	Kenya Vision 2030	<p>The Kenya Vision 2030 is the national long-term development blue-print that aims to transform Kenya into a newly industrializing, middle-income country providing a high quality of life to all its citizens by 2030 in a clean and secure environment. The Vision comprises of three key pillars: Economic; Social; and Political. The Economic Pillar aims to achieve an average economic growth rate of 10 per cent per annum and sustaining the same until 2030. The Social Pillar seeks to engender just, cohesive and equitable social development in a clean and secure environment, while the Political Pillar aims to realise an issue-based, people-centred, result-oriented and accountable democratic system. The three pillars are anchored on the foundations of macroeconomic stability; infrastructural development; Science, Technology and Innovation (STI); Land</p>	<p>The social pillar which among others envisions for Kenyans a high quality of life in a clean and secure environment implies sustainable utilization of the country's natural resources including genetic resources the subject of ABS domestication</p>	<p>Vision 2030 Secretariat</p>





		Reforms; Human Resources Development; Security and Public Sector Reforms www. kenyavision2030.gov		
4	International Treaty on Plant Genetic Resources for Food and Agriculture (FAO ITPGRFA)	Article 9 of the Treaty recognizes Farmers' Rights to access genetic resources, to use and save seeds, under national laws.	Preamble of Nagoya Protocol recognizes that the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture was developed in harmony with the Convention on Biodiversity, Therefore, access to 64 plant genetic resources managed under ITPGRFA multilateral system are exempted from the requirements of CBD ABS Regime.	National Gene Bank, KARI
5	EAC Protocol	Article 10 on management of Biodiversity,	This protocol details the	EAC



	on Environment and Natural Resources Management	11 management of forest and tree resources, 12 on management of wildlife resources, 13 on management of water resources, 14 on Sustainable management and wise use of wetland resources, 15 on management of Fisheries resources EAC Protocol on Environment and Natural Resources Management, 1999, Online: www.eac.int/environment	commitment of party states to develop, harmonise, adopt and implement common policies, laws, strategies, plans and programmes relating to conservation and use of biological resources in the EAC. Noting: Disputes arising between and among member states are to be referred to the East African Court of Justice.	secretariat, Ministry of EA affairs, Commerce and Tourism, Committee on Environment and Natural Resources
6	The Swakopmund Protocol on the Protection of Traditional Knowledge and Expression of Folklore, 2007	This treaty negotiated under ARIPO is important for the protection of IP. Accessed at: www.kenyalaw.org/.../Swakopmund-Protocol-on-the-Protection-of-Traditional...	This is an important part of international law, which Kenya recognizes, but is yet to sign this important treaty for the protection of TK and the relevant institutions should therefore champion it through the relevant parliamentary select committee for ratification.	Ministry of Culture, Sports and the Arts, NMK, Ministry of Industrialization, KIPI, KIRDI, NACOSTI

B. POLICY DOCUMENTS				
1	National Environment Policy, 2013	<p>Part 4.0: Management of Ecosystems and Sustainable use of Natural resources, Specific to ABS the government will;</p> <ul style="list-style-type: none"> Regulate and encourage sustainable utilisation and bioprospecting of biological resources in accordance with international law. Develop mechanisms to ensure that the benefits arising from access to genetic resources, including intellectual property rights, traditional knowledge and technology are shared equitably with communities living in areas where the Genetic material originated. <p>www.environment.go.ke/wp-content/uploads/2014/01/NATIONAL-ENVIRONMENT-POLICY-20131.pdf</p>	The policy specifically alludes to the sustainable use of GR and associated TK and the appropriate ABS arrangements including protection of TK.	Ministry of Environment, Water and Natural Resources
2	Draft Legal Framework for	<p>The purpose is to:</p> <ol style="list-style-type: none"> protect traditional knowledge (TK) 	The draft framework does not include access to GR and BS	KECOBO, Department

	the Legal Protection of Traditional Knowledge and Traditional Cultural Expressions, 2013	holders against any infringement of their rights, 2. Protect TK and traditional cultural expressions (TCEs) against misappropriation, misuse and unlawful exploitation beyond their traditional context, 3. Protect sustainable utilization of TK and TCEs and ensure communities receive compensation for the use of their cultures, knowledge and heritage for national development	But rather protection of TK and TCEs associated with GR.	of Culture and KIPI
3	"Draft Policy on Traditional Medicine and Medicinal Plants", Nairobi, 2007. National Coordinating Agency for Population and	The draft policy is aimed at achieving conservation of medicinal plants, equitable sharing of benefits, and enhancing production and domestication, while ensuring the safety and efficacy of the products. It will also gives guidance to practitioners, consumers and regulators.	The draft policy ignored issues of ABS and IPRs. Other Policy Documents are being developed e.g. "Natural Products Industry Initiative" and "Alternative Medicine Regulation Bill"	Department of Culture, Ministry of Health and NEMA.



	Development (NCAPD),			
4	National Forest policy, 2014	This policy is aimed at the sustainable development, management, utilization and conservation of forest resources and equitable sharing of accrued benefits for the present and future generations of the people of Kenya. http://www.kenyaforestservice.org/documents.pdf	ABS issues are at the heart of this forestry sector policy document.	Ministry of Environment, Water and Natural Resources, KFS
5	Natural Products Industry Initiative Draft Policy, 2012	The draft policy articulates policy issues involved in use of genetic resources in development of natural products in Kenya	The draft policy is yet to be adopted	IPR, NMK, KIPI
6	Kenya National Biodiversity	Part 4 The National Strategy elaborates issues on the in-situ and Ex situ biodiversity	The National strategy identifies goals and objectives	Ministry of Environment,



	Strategy and Action Plan, 2000	conservation in the country and attendant issues. www.cbd.int/doc/world/ke/ke-nbsap-01-en.pdf	and analyses the gaps between the reality and the aspirations stated in the goals and objectives. It states the issues and provides strategies that need to be undertaken in order to mitigate against the current threats to biodiversity. Each article of the CBD is discussed, stating what needs to be done and how it should be done.	Water and Natural Resources
C. NATIONAL LAWS				
1	The Government of Kenya, 2010. "The Constitution of Kenya" Nairobi, Kenya: Government	Preamble: Respectful of the environment, which is our heritage, and determined to sustain it for the benefit of future generations Article 2 (1) This Constitution is the supreme law of the Republic and binds all persons and all State organs at both levels of government. (5) The general rules of	The preamble alludes to the fact that the environment is our heritage and pledges to sustain it for the benefit of all. Article 2 recognizes that the constitution is the supreme law of Kenya and all are bound by it.	The Executive, Judiciary, Parliament, County Governments , Government

	<p>Printer. 2010</p>	<p>international law shall form part of the law of Kenya.</p> <p>(6) Any treaty or convention ratified by Kenya shall form part of the law of Kenya under this Constitution.</p> <p>Article 10 (2) The national values and principles of governance include—(a) patriotism, national unity, sharing and devolution of power, the rule of law, democracy and participation of the people; (b) human dignity, equity, social justice, inclusiveness, equality, human rights, non-discrimination and protection of the marginalized; (c) good governance, integrity, transparency and accountability; and (d) sustainable development.</p> <p>Article 11 (a) promote all forms of national and cultural expression through literature, the arts, traditional celebrations, science, communication, information, mass media,</p>	<p>Subsection (6) is formally legislated under the treaty making and ratification act No. 45 of 2012.</p> <p>Article 10, emphasizes national values and principles of governance that are important to ABS are values such as patriotism and participation of the people.</p> <p>Article 11 recognizes and promotes all forms of expressions many of which are accessed by other parties and engenders IP protection.</p>	<p>line Ministries, departments, State corporations, including NEMA and Others</p>
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		<p>(b) to have obligations relating to the environment fulfilled under Article 70.</p> <p>Chapter V land and environment</p> <p>Article 60 Principles of Land Policy</p> <p>(1) (e) sound conservation and protection of ecologically sensitive areas; (f) elimination of gender discrimination in law, customs and practices related to land and property in land;</p> <p>Article 69 (1) (a) ensure sustainable exploitation, utilization, management and conservation of the environment and natural resources, and ensure the equitable sharing of the accruing benefit (c) protect and enhance intellectual property in, and indigenous knowledge of, biodiversity and the genetic resources of the communities; (d) encourage public participation in the management, protection and conservation of the environment; (e) protect genetic</p>	<p>specific policies and legislation are important to ABS.</p> <p>Article 60 alludes to use of land sustainably.</p> <p>Article 69 obligates the state to ensure sustainable exploitation, utilization, management and conservation of the environment and natural resources, and ensure the equitable sharing of the accruing benefits; protect and enhance protection of intellectual property and indigenous knowledge, biodiversity and the genetic resources of the communities; protect genetic resources and biological diversity; utilize the</p>	
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		<p>resources and biological diversity; (g) eliminate processes and activities that are likely to endanger the environment; and (h) utilise the environment and natural resources for the benefit of the people of Kenya.</p> <p>(2) Every person has a duty to cooperate with State organs and other persons to protect and conserve the environment and ensure ecologically sustainable development and use of natural resources.</p> <p>Article 70 (1) If a person alleges that a right to a clean and healthy environment recognised and protected under Article 42 has been, is being or is likely to be, denied, violated, infringed or threatened, the person may apply to a court for redress in addition to any other legal remedies that are available in respect to the same matter.</p> <p>Article 71 Agreements relating to natural resources</p> <p>1 (a) Involves the grant of a right or</p>	<p>environment and natural resources for the benefit of the people of Kenya.</p> <p>Article 71 on granting access to use of natural resources. Although it but does not qualify these as including biological and genetic resources, it is relevant in so far as some biological or GR may be affected in the process.</p> <p>The fourth schedule on separation of function between the national and</p>	
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		<p>concession by or on behalf of any person, including the national government, to another person for the exploitation of any natural resource of Kenya; and this is subject to other legislation to be enacted.</p> <p>Fourth Schedule on Distribution of Functions</p> <p>Part 1 National Government</p> <ol style="list-style-type: none"> 1. Foreign affairs, foreign policy and international trade. 2. The use of international waters and water resources. 3. Immigration and citizenship. 8. Courts. 9. National economic policy and planning. 12. Intellectual property rights. 16. Universities, tertiary educational institutions and other institutions of research and higher learning and primary schools, special education, secondary schools and special education institutions. 	<p>county government provides some challenges to the management of biological resources and GR to the extent that the resources extend across county boundaries and economic focus may differ among counties. In such cases, the matter is to be referred to the National government. However, all research functions are under the National Government.</p>	
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		<p>22. Protection of the environment and natural resources with a view to establishing a durable and sustainable system of development, including, in particular—(a) fishing, hunting and gathering; (b) protection of animals and wildlife; (c) water protection, securing sufficient residual water, hydraulic engineering and the safety of dams; and (d) energy policy.</p> <p>Part 2 County Governments</p> <p>1. Agriculture, including— (a) crop and animal husbandry;(b) livestock sale yards;(c) county abattoirs;(d) plant and animal disease control; and (e) fisheries.</p> <p>4. Cultural activities, public entertainment and public amenities, including— (g) museums; (h) sports and cultural activities and facilities; and (i) county parks, beaches and recreation facilities.</p> <p>7. Trade development and regulation,</p>		
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		<p>including—(a) markets; (b) trade licenses (excluding regulation of professions); (c) fair trading practices; (d) local tourism; and (e) cooperative societies</p> <p>SIXTH SCHEDULE –TRANSITIONAL AND CONSEQUENTIAL PROVISIONS</p> <p>Part 2 Existing Obligations, Laws and Rights</p> <p>6. The existing rights, duties and obligations of the state, organ or state officer are upheld until they are reviewed to conform to the new constitution</p> <p>7. Existing laws remain in force until they are reviewed to conform to the new constitution</p> <p>8. Freehold interest in land holdings, rights and agreements relating to natural resources held by a non-citizen revert to the republic of Kenya at the end of the period.</p>		
2	Environmental Management	Requires the Authority under; Section 50; to prescribe measures for	Section 50 and 51 gives NEMA an oversight role of	NEMA



	<p>and Coordination Act (EMCA) 1999</p>	<p>conservation of biological diversity in consultation with relevant lead agencies Section 51; to prescribe measures to ensure Conservation of Biological resources <i>in situ</i> in consultation with relevant lead agencies Section 52 to prescribe measures to ensure Conservation of biological resources <i>ex situ</i> in consultation with relevant lead agencies Section 53 (1) to, issue Guidelines and prescribe measures for the sustainable management and utilization of Genetic resources of Kenya for the benefit of the people of Kenya. (2) Without prejudice to the general effect of subsection (1), the guidelines issued or Measures prescribed under that subsection shall specify – (a) Appropriate arrangements for access to genetic resources of Kenya <u>by non-citizens</u> of Kenya including the issue of licenses and fees to be paid for that access; (b) measures for regulating the import or</p>	<p>coordinating matters of biological conservation in consultation with relevant lead agencies. Section 53 is the most important section specific to regulating matters that relate to access to GR and BS in Kenya in accordance with CBD. These provisions have very little to do with other Conventions on GR such as CITES and ITPGRFA. This section when applied in respect of executing an MTA has to co- reference with the relevant sections of the Seed and Plant varieties act Cap</p>	
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		<p>export of germplasm;</p> <p>(c) the sharing of benefits derived from genetic resources of Kenya;</p> <p>(e) measures necessary to regulate the development, access to and transfer of biotechnology; and (f) any other matter that the Authority considers necessary for the better management of the genetic resources of Kenya.</p>	<p>325 in so far as access to germplasm under ITPGRFA are concerned</p>	
3	Wildlife Conservation and Management Act, 2013	<p>The entire Act, including sections 10, Section 22(2) Any person desirous of undertaking bioprospecting involving any wildlife resources may apply to the Authority for a permit in a prescribed format and on payment of prescribed fees.</p> <p>(3) The Authority shall in reviewing the application ensure that any interests of the following stakeholders may have in the proposed bio-prospecting are protected-</p> <p>(a) a person, including a public or private organization or institution or community,</p>	<p>Provides for application for certain permits (in form of PIC) prior to access. There is need to read these sections together with the ABS Legal Notice No. 160 of 2006.</p>	<p>KWS as a Lead Agency</p>

		<p>providing or giving access to the wildlife resource to which application relates;</p> <p>(b) a community- (i) whose traditional uses of the wildlife resources to which the application relates have initiated or will contribute to or form part of the proposed bio-prospecting; and (ii) whose knowledge of or discoveries about the wildlife resource to which the application relates are to be used for the proposed bioprospecting.</p> <p>Section 72. (1) Utilisation and exploitation of wildlife resources by any person whether individual land owner or in a conservation area, and wherever else shall be practiced in a manner that is sustainable and in accordance with regulations made under this Act.</p> <p>Part VII Conservation orders, easements and incentives</p> <p>Part (X) \licensing and regulation</p>		
4	Forest Act 2005	<p>The entire Act particularly;</p> <p>Sections 33 (1) The President may, on the</p>	<p>Trees are biological and GR thus any executive order may</p>	KFS



		<p>advice of the Board, by order published in the Gazette, declare any tree, species or family of tree species to be protected in the whole country or in specific areas thereof, and the Board shall cause this information to be disseminated to the public.</p> <p>(2) Any person who fells, cuts, damages or remove, trades in or exports or attempts to export any protected tree, species or family of trees or regeneration thereof or abets in the commission of any such act commits an offence.</p> <p>Section 39 2 (c) ensure that the forest areas under his management are maintained for the conservation of biodiversity, cultural or recreational use</p>	<p>directly affect on-going ABS arrangements.</p> <p>The Act underpins sustainable utilization of forests.</p>	
5	<p>National Museums and Heritage act, 2006</p> <p>And the</p>	<p>The entire Act, consolidates the law relating to national museums and heritage; provides for the establishment control, management and development of national museums and the identification, protection, conservation and transmission of the cultural and natural</p>	<p>Issues of Access to cultural and natural heritage, particularly monuments, antiquities as defined in this act are liable to challenges in law enforcement and to</p>	NMK



	<p>National Museums and Heritage (Antiquities dealers) (Licensing) Rules, 2009</p>	<p>heritage of Kenya; ..; and for connected purposes. Part V on searches and discoveries, sections 27 exploration licenses, 28 conditions and forms of exploration licenses, 29 entry on land under exploration licence, 31 restriction on moving objects and 32 offences Part VI section 34 (a-d) control of access etc to protected area</p> <p>77 amends EMCA Section 38 to (jj) take into account and record all monuments and protected areas declared or deemed to have been declared by the Minister under this Act. Similarly, other related legislation have been amended to protect monuments, antiquities and similarly protected objects.</p> <p>Also, requires foreign investors in heritage transactions to comply with rules relating to investment in Kenya.</p>	<p>infringement on access rights of other users.</p>	
<p>6</p>	<p>Universities Act, 2012</p>	<p>PART I Preliminary</p> <p>3.(1) The objectives of university education shall include —</p>	<p>Describes access to GR for education, research and transfer and therefore has a</p>	<p>Universities and Research Institutions</p>



	<p>(a) advancement of knowledge through teaching, scholarly research and scientific investigation;</p> <p>(b) promotion of learning in the student body and society generally;</p> <p>(c) promotion of cultural and social life of society;</p> <p>(d) support and contribution to the realization of national economic and social development;</p> <p>(e) promotion of the highest standards in, and quality of, teaching and research; education, training and retraining higher level professional, technical and management personnel;</p> <p>(g) dissemination of the outcomes of the research conducted by the university to the general community;</p> <p>(h) facilitation of life-long learning through provision of adult and continuing education;</p> <p>(i) fostering of a capacity for independent</p>	<p>direct bearing to ABS Regulations</p>	<p>and Centres</p>
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		critical thinking among its students; and society		
7	NACOSTI Act, 2013	<p>PART IV – LICENSING OF RESEARCH</p> <p>12. (1) Subject to the provisions of any other law, a person shall not undertake scientific research in Kenya without obtaining a licence under this Act (2) Subsection (1) shall not apply to a person conducting scientific research under a university or a research institution programme.</p> <p>(3) Any person undertaking or intending to undertake research in science and technology in the country, or who accesses, handles, or transfers any material or technology or moves it within, from or into the country, shall apply to the Commission for the grant of a licence in accordance with this Act</p> <p>(4) Notwithstanding the generality of subsection (2), the Cabinet Secretary may, on recommendation of the Commission, by</p>	<p>NACOSTI licenses users of GR for research and transfer of materials. The licence replaces Research Clearance Certificate in the new Act required under the National ABS Regulations.</p> <p>However, subsection (1) exempts local academic and research institutions collaborating with foreign partners and potentially oblivious of their potential to generate vulnerable IP. In section 13 the law is careful to underscore the protection of the GR during evaluation of research permit application. Section 15 outlines offences</p>	NACOSTI



		<p>notice in the Gazette, exempt any research from the requirements of subsection (1).</p> <p>(5) Notwithstanding the provisions of subsection (1), no licence shall be granted for any research involving activities which— (a) may adversely affect the culture of any community in Kenya; (b) may adversely affect the environment; (c) may result in the exploitation of intellectual property rights of communities to their traditional knowledge. (d) may, in the view of the Commission, adversely affect the lives of Kenyans.</p> <p>13. (1) The Commission shall, upon receipt of an application under section 12, evaluate the application, and if satisfied that the conduct of the research is beneficial to the country, and, that the research shall not adversely affect any aspect of the nature, environment or the security of the country, issue to the applicant a licence in the prescribed form. (3) The Commission shall</p>	<p>against this law.</p>	
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		<p>keep a register of all persons granted licence under this Part, which register shall be available for public inspection during normal working hours free of charge 14. Any person issued with a licence pursuant to this Part shall adhere to such procedures, standards, code of ethics and guidelines as may be prescribed by regulations made under this Act.</p> <p>15. Offences:</p> <p>(1) Any person who- (a) accesses, handles, transacts, transfers or moves any specified technology or any material necessary for scientific research within, into or from Kenya without a licence issued under this Act; or (b) contravenes the provisions of section 12, commits an offence and shall, in addition to any other penalty which may be provided for in this Act or any other written law, be liable on conviction to a fine not exceeding five million shillings or to</p>		
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		<p>imprisonment for a term not exceeding four years, or both. (2) The Court convicting a person under subsection (1) may in addition to any penalty imposed thereunder, order the confiscation of the materials in respect of which the offence is committed, and may bar the person so convicted from undertaking any further research in the country or transferring or moving any substance or material in or out of the country.</p> <p>(3) For the avoidance of doubt, the technologies or materials imported into or exported out of Kenya and declared under— (a) the Industrial Property Act; (b) the Seeds and Plant Varieties Act;(c) the Wildlife (Conservation and Management) Act; (d) the Customs and Excise Act; (e) the Biosafety Act; or any other written law shall be deemed to be technologies or materials to which this section applies.</p>		
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8	Biosafety Act, 2009	<p>Part II, Section 4 on Objectives:</p> <ol style="list-style-type: none"> 1 .To facilitate responsible research and minimize risks that may be posed by genetically modified organisms; 2. To ensure adequate level of protection in the development, transfer, handling and use of genetically modified organisms that may have an adverse effect on the health of the people and the environment; and 3. To establish a transparent, science based and predictable process for reviewing and making decisions on the development, transfer, handling and use of genetically modified organisms and related activities. 	<p>The Act can be used promote safe modern biotechnology research on accessed GR and protection of local GR from effects of such research</p>	<p>Agriculture, Fisheries and Food Authority, National Biosafety Authority (NBA)</p>
9	Industrial Property Act, 2001	<ol style="list-style-type: none"> 1. Section 2 on interpretations: “Utility model” means any form, configuration or disposition of element of some appliance, utensil, tool, electrical and electronic circuitry, instrument, <u>handicraft</u> 	<p>This section provides for protection of simple innovations such as those found in local communities that do not require to involve any “inventive step”</p>	<p>Kenya Industrial Property Institute (KIPI)</p>



		<p>mechanism or other object or any part of the same allowing a better or different functioning, use, or manufacture of the subject matter or that gives some utility, advantage, environmental benefit, saving or technical effect not available in Kenya before and includes micro-organisms or other self-replicable material, products of genetic resources, <u>herbal</u> as well as nutritional formulations which give new effects.</p> <p>2. "Innovation" means utility models, technovation models, and industrial designs and any other non-patentable creations or improvements that may be deemed as deserving specified industrial property rights;</p>	<p>This definition ensures that even the simplest technologies and processes thereof are include in the IP regime</p>	
12	The Kenya	Part VI on Immigration Controls, sections	In section 36, this act refers to	Department



	Citizenship and Immigration Act, 2011, No. 12 of 2011	35-52on issuance of Visa, residence, permits, obligations and proper documentation with regard to being in Kenya legally. Accessed at: Kenyalaw.org/Amendment Acts/2011/ The Kenya CitizenshipandImmigration_Act2011 Accessed at:	the science and technology Act and more specifically to the Procedures and Guidelines for Research Authorization in Kenya of 2009. http://www.ncst.go.ke/index.php/2013-07-08-50-21/research-license	of Immigration
13	The Seed and Plant Varieties Act, Cap 325	27A. (1) There is established a National Plant Genetic Resources Centre which shall be responsible for the conservation and sustainable utilization of plant biodiversity in Kenya. (2) The functions of the National Plant Genetic Resources Centre shall be to (a) protect the ownership of indigenous seeds and plant varieties, their genetic and diverse characteristics, associated indigenous knowledge and its use by these, communities of Kenya; (b) carry, out inventories by evaluating and mapping plant genetic resources distribution in the	Granting Access permits, under the EMCA and the ABS regulations, need to cross reference with this act, which is yet to be repelled, especially as regards executing the MTA as the needed document may well be a SMTA under the ITPGRFA in terms of 1. farm-saved seeds, 2. protection of varieties derived from	KEPHIS



		<p>country;</p> <p>(c) conserve plant genetic diversity by devising and implementing management procedure, including ex-situ and in-situ maintenance;(d) co-operate with international institutions on matters relating to plant genetic resources, including the administration of material transfer agreements; (e) ensure safe custody and accessibility of all plant bred and naturally occurring germplasm; (f) document and disseminate plant genetic resources, data and information to users; (g) collaborate with and institutions of higher learning to address adaptive, applied and strategic research; (h) enhance capacity for the effective conservation of plant _genetic resources; and (i) advice tit Government on policies governing the conservation and use of plant genetic resources.(3) There shall be a National Plant Genetic • Resources Centre</p>	<p>landraces,</p> <p>3. farmers' rights on landraces (being enjoined in exclusive provisions for breeders' rights)</p>	<p>National Gene Bank</p>
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		Committee which shall provide oversight on matters relating to the centre.(4) The Minister may make regulations to provide for the membership and functions of the Committee.		
14	The Agriculture, Fisheries and Food Authority Act, 2013	Part VI refers the respective roles of national and county governments, viz the constitution of Kenya 2010, part 2 of the 4 th Schedule Section 43 prohibits export of some agricultural products. Kenyalaw.org/Amendment Acts/2013/The Agriculture, Fisheries and Food Authority Amendment Act 2013.	Restrictions implied by ITPGRFA apply	Agriculture, Fisheries and Food Authority
15	Customary Law	Traditional knowledge can be protected under customary law	Policy guidelines are needed to enable appropriate protection of associated TK	Judiciary and case by case
16	Law of Contract	The Law of Contract is sometimes used to protect trade secrets under confidentiality clauses NDAs.	Addresses issues on breach of contract, and provisions on penalties and redress with	Judiciary

			regard to MAT and PIC issues	
17	The treaty making and ratification act No. 45 of 2012	4. (1) This Act applies to treaties which are concluded by Kenya after the commencement of this Act. (2) This Act shall apply to— (a) multilateral treaties; (b) bilateral treaties which deal with— (iv) the relationship between Kenya and any international organisation or similar body; and (v) the environment and natural resources. <i>Accessed at; kenyalaw.org/kl/.../Acts/TreatyMakingandRatificationNo45of2012.doc</i>	All treaties shall be subject to cabinet approval and approval by parliament if both bodies have no reservations or with explicitly stated reservations. Also, the line ministry and and state department/body in charge must undertake to create awareness about the ratified treaty to the public.	
NATIONAL REGULATIONS				
18	Legal Notice No. I60 of 2006 - ABS Regulations	Legal Notice No. I60, The Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006	The Regulations provide for PIC prior to Access Permit but do expressly mention PIC with MAT. They also mention MTA but do not provide for guidelines. There is need to review the Legal Notice to	NEMA and Lead Agencies



			align it with the Nagoya Protocol and other national legislations	
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8 GLOSSARY

Access - obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bio-prospecting, conservation, industrial application or commercial use.

Agreement - any agreement involving Mutually Agreed Terms (MAT).

Benefit-Sharing - sharing of benefits that accrue from the utilization of genetic resources, their progeny, derivatives and associated traditional knowledge, practices and innovations. The benefits include both monetary and non-monetary returns such as but not limited up-front payments, royalties, salaries, institutional development and strengthening, technical and academic training, the transfers of technology and information exchange and sharing as specified in this agreement.

Commercial purpose - sale, lease, license, or other transfer of any biological material or its progeny, unmodified derivatives, modifications, inventions, or product for value received, including but not limited to scientific research, uses of any biological material or progeny, unmodified derivatives, modifications, inventions, or products by any person (including but not limited to provider and recipient) in the performance of any contract research, screening compound /metagenomic libraries, or the conducts of research activities that results in sale, lease, license, or other transfer of any progeny, unmodified derivatives, modifications, inventions, or products.

Commercialization - include, but not be limited to: sale, licensing, filing a patent application, obtaining, application, or transferring intellectual property rights or any other manner, commencement of product development, undertaking market research and seeking pre-market approval.

Communities - a group of indigenous and local peoples of a locality from which the genetic resources will be accessed from.

Lead Agency - a government agency that is a relevant knowledge or resource base public institutions defined in the THIRD SCHEDULE (s.37(1)(d), 70(2)) of EMCA, 1999. Bodies and or institutions established by the government, to manage certain environmental resources in consultation with NEMA under EMCA, and are responsible for granting PIC within their jurisdiction.

Competent National Authorities (CNAs) are bodies established by governments and are responsible for granting access to users of their genetic resources, and representing providers on a local or national level. **Convention on Biological Diversity (CBD)** - 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 genetic resources

Derivatives - include but not be limited to modified or unmodified extracts and any compounds or chemical structure based on or derived from plant, animal, fungal and microbial genetic resources and their progeny, including analogues.

Designated National Authority - National Environment Management Authority (NEMA, also referred to as the Authority).

Designated Repository Centers - legally mandated national centers in which voucher specimens and /or duplicates of the transferred materials shall be deposited and maintained.

Duplicates shall a referenced representative sample of the genetic resource accessed by an access permit holder.

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

Genetic Resources - any biological material of plant, animal, microbial, fungal or other origin containing functional units of heredity of actual or potential value.

Holotype shall - a single specimen chosen for designation of new species.



"In situ" genetic resources are those found within ecosystems and natural habitats.

"Ex situ" genetic resources are those found outside their normal ecosystem or habitat, such as in botanical gardens or seed banks, or in commercial or university collections.

Information - any TK, maps, images, photographs, plans, manuscripts, records, reports, recommendations, estimates, documents and any other data arising out of genetic resource(s).

Intellectual Property - any creation, innovation, invention, information or data resulting from human intellect or mind and includes patents, copyright and designs.

Invention - innovation or discovery that is or may have patentable or is otherwise protected under Industrial Property Act, 2001, Plant and Seed Varieties Act (Cap 326), Copyrights Act 2001), Films and Stage Plays Act Cap 222 of 2009.

Local Communities - the indigenous peoples of a locality from which the resource(s) are accessed.

Material Transfer Agreement - an agreement to transfer the genetic resources negotiated between the relevant lead agency and the recipient of the genetic resources.

Modifications - substances created by recipients that are derived from/ contain /incorporate / specimens, progeny or derivatives.

Monitoring and Evaluation Committee - a committee established to monitor, evaluate and audit the utilization of genetic resource(s).

Mutually agreed terms (MAT) - an agreement reached between the providers of genetic resources and users on the conditions of access and use of the resources, prior informed consent and the benefits to be shared between both parties.



Nagoya Protocol - refers to an international agreement signed by parties to CBD that provides for access to genetic resources, fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

National Focal Point (NFP) – Government Organ that is responsible for providing this information and which facilitates access, users need a clear and transparent process that details who to contact and what the requirements and processes are in provider countries in order to gain access.

Person - individual, firm or organization as elaborated in EMCA.

Prior Informed Consent (PIC) - A consent obtained by a user from the provider after fully disclosing all the required information that permits access to genetic resources and associated traditional knowledge.

Product - any modification, invention, or any other commercially valuable or other useful or potentially useful material, compound, or useful or potentially useful combination of compounds, proteins, or metabolites recovered, obtained, derived, resulting or otherwise isolated by scientific research conducted from progeny, unmodified derivatives, or research specimen originally acquired from the provider, or any derivative or analog of such material compound, proteins or other isolates or any discovery that is or may be patentable or otherwise protected under Kenyan Industrial Property Law, or any novel variety of plants that is or may be protectable under the Plant and seed varieties Act and developed from progeny, unmodified derivatives or research specimen originally acquired from the provider.

Progeny - unmodified descendant of the accessed genetic resource.

Providers - the person(s) providing the genetic resources and / or associated knowledge e.g. lead agency, individual or community.

Recipient - person(s) / party receiving the genetic resource under this agreement

Sales - the gross income resulting from the commercialization of a product by the recipient

Sample - an agreed quantity of biological resources collected from the area of access.

Specimen - collections of genetic resources under designated repository institutions.

Third Party - any person other than 'Designated National Authority', Competent Authority, the provider and the user.

Traditional Knowledge (TK) - encompass traditional and tradition based literary, artistic or scientific works; inventions; scientific discoveries; names and symbols; undisclosed information; and all other traditional and tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, folklore, literary or artistic fields..

Unauthorized Disclosure - the placement of confidential information including indigenous TK into the public domain by publication or disclosure to a Third Party without the written prior informed consent of the original holders (s) of that knowledge.

Unmodified Derivatives - substances created by recipient that constitute unmodified functional subunits or products expressed by Material. For example and not limited to, subclones of unmodified celllines, purified or fractionated subsets of material, proteins expressed by DNA/RNA and amino acids obtained from material or monoclonal antibodies secreted by hybridoma cell line.

User - any person who has applied to access genetic resources.



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