THE ABS CAPACITY DEVELOPMENT INITIATIVE

L'INITIATIVE DE RENFORCEMENT DES CAPACITES POUR L'APA

National Study on ABS Implementation in South Africa

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The ABS Capacity Development Initiative, in collaboration with the Governments of Brazil, India and South Africa, commissioned national studies to review each country's experiences with Access and Benefit Sharing. Lessons learned from these experiences will inform the global implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from its Utilization (Nagoya Protocol). These studies were prepared to provide background information in preparation for the first Dialogue on Practical Ways Forward for the Implementation of the Nagoya Protocol, hosted by the Government of South Africa on 30-31 January 2014 in Cape Town, South Africa and the second Dialogue on the same topic, co-organized with the Ministry of Environment and Forests of India, from 4-6 August 2014 in Goa, India.

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List of Abbreviations

ABS	Access and Benefit Sharing
BABS	Bioprospecting, Access & Benefit Sharing
BSA	Benefit Sharing Agreement
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of wild flora and fauna
DAFF	Department of Agriculture, Forestry and Fisheries
DEA	Department of Environmental Affairs
DST	Department of Science and Technology
DTI	Department of Trade and Industry
IBR	Indigenous Biological Resources
IKS	Indigenous Knowledge Systems
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
LMMC	Like-Minded Mega-Diverse Countries
MAT	Mutually Agreed Terms
MEC	Member of Executive Committee
MLS	Multilateral System
MTA	Material Transfer Agreement
NEMA	National Environmental Management Act
NEMBA	National Environmental Management: Biodiversity Act
PIC	Prior Informed Consent
TK	Traditional Knowledge
TOPS	Threatened or Protected Species

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1. INTRODUCTION

South Africa is rich with natural resources, it being the third (3rd) most biologically diverse country following Indonesia and Brazil with a high incidence of endemic species and is a member of the Like-Minded Mega-Diverse Countries (LMMC). It represents about 2% of the world's landmass and has 10% of the world's plants, 7% of all mammals, birds and reptiles, and 15% of all known marine species. International and local trade in biological resources has led to an increase in the utilisation of a valuable but limited resource in South Africa. In addition, there has been a growing concern that holders of the traditional knowledge of the useful properties of biological resources are not recognised and often do not benefit from the commercial utilization of such resources. As a result, a number of international and national policies, laws and regulations have been introduced to redress inequality in the commercial utilization of biological resources. South Africa has made significant progress in developing the policy and legislative instruments necessary to guide and regulate the commercial or industrial exploitation of indigenous biological/genetic resources and/or associated traditional knowledge for bioprospecting and/or biotrade in the country, but is faced with challenges with the application and implementation of these instruments, while at the same time stimulating the growth of this economic sub-sector in the country.

One of the international instruments to regulate the utilization of genetic resource is the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (in short referred to as "The Nagoya Protocol on ABS" or "the Nagoya Protocol" which was adopted in 2010 at the 10th meeting of the Conference of the Parties to the Convention Biological Diversity (CBD). It sets in place a legally-binding agreement specific to Access and Benefit Sharing (ABS). South Africa is one of the contracting parties to the CBD and the Nagoya Protocol on ABS, and has promulgated and implemented legislation to regulate bioprospecting, access and benefit-sharing activities even before the adoption of the Nagoya Protocol on ABS in accordance with the obligations as provided in the CBD. South Africa ratified the Nagoya Protocol in January 2013.

The Nagoya Protocol has set out core obligations for its contracting Parties to take appropriate measures related to access to genetic resources, benefit-sharing and

compliance. Measures that ought to be put in place for the effective implementation of this Protocol include amongst others; establishing clear rules and procedures for prior informed consent and mutually agreed terms, ensuring that benefit-sharing measures put in place do provide for the fair and equitable sharing of benefits arising from the utilization of genetic resources with the contracting party providing genetic resources and also ensuring that appropriate obligations that support compliance with the domestic legislation or regulatory requirements of the contracting party providing genetic resources are spelt out.

1.1 BACKGROUND

The "ABS Capacity Development Initiative" has initiated studies to review the national experience of Brazil, India and South Africa respectively with respect to ABS implementation in order to draw lessons that can inform the development of national measures in conformity with the Nagoya Protocol on ABS.

National studies are to be carried out by national consultants in each country in order to examine what is the ABS framework in place, what were lessons learned from their implementation and how these lessons can be taken into account in the implementation of the Nagoya Protocol on ABS . Each of the three studies is to provide an overview of the existing ABS frameworks in place at the country level and this report seeks to address the South African perspective in response to the set questions provided by the "ABS Capacity Development Initiative".

2. NATIONAL FRAMEWORK

Who are the competent national authorities?	The Minister of Water and Environmental Affairs and thus the national Department of Environmental Affairs (DEA) as the environmental regulator in the country, is the competent national authority. The Minister of Water and Environmental Affairs is the issuing authority for (a) bioprospecting permits in the country and (b) integrated export and bioprospecting permits, if the indigenous biological resources are being exported for the purposes of bioprospecting. The respective provincial Member of Executive Committee (MEC) is the issuing authority for export permits of indigenous biological resources for purposes of research other than bioprospecting.
Is there one or more?	The DEA is the only competent national authority. However, it is important to note that according to the Constitution of South Africa, nature conservation (excluding national parks, national botanical gardens and marine resources) are a concurrent national and provincial competence in the country. Various government departments are involved in administering particular laws which regulate ABS in South Africa. The Department of Environmental Affairs and provincial environment and conservation departments are the responsible institutes for regulation and implementation of environmental legislative imperatives. The Department of Trade and Industry (DTI) is the responsible institute for regulation and implementation of the intellectual property rights legislative imperatives and the Department of Science and Technology (DST) is the responsible institute for the protection, promotion, development and management of Indigenous Knowledge Systems (IKS) through the IKS Policy.
How were they established?	The Government of South Africa is a three – tier system constituting of the National, Provincial and Local levels of Government all having legislative and executive authority in their spheres. The Constitution of South Africa defines them as being "distinctive, interdependent and interrelated" and the Government system recognises Traditional Authorities. The National Competent Authority was established through the promulgation of National Environmental Management: Biodiversity Act (NEMBA).

	The National Government of South Africa is comprised of Parliament, Cabinet and various Departments. These components carry out functions as outlined in the Constitution and in legislation enacted by Parliament. The Departments that make up the national administration are charged with implementing legislation and providing services to the public.
What is the scope of the measures in place?	The National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) (NEMBA), which enacts the White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity, is the legislative instrument which governs the bioprospecting and the use of indigenous biological resources in the country. The Act effectively sets out South Africa's domestic objectives to address the obligations of the Convention on Biological Diversity. Apart from providing key definitions of the components addressed by the Act, it also provides two crucial (but not only these) components to the bioprospecting sector, namely: (i) that the state is the trustee of the biological diversity in the country with the state assuming responsibility to manage, conserve and sustain South Africa's biodiversity and its components and genetic resources; (ii) and the ABS legal framework for South Africa, which is contained in Chapter 6 of the Act, with the objective (a) to regulate bioprospecting involving indigenous genetic and biological resources ; (b) to regulate the export from the Republic of indigenous genetic and biological resources for the purpose of bioprospecting or any other kind of research; and (c) to provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous genetic and biological resources; and (d) to ensure the nation's indigenous genetic and biological resources are developed and utilised in a sustainable manner while promoting social and economic development, in particular in the area where the indigenous genetic or biological resource and traditional knowledge is accessed.
Who owns genetic resources in the country? Who owns biological resources?	Despite the State being the trustee of biological diversity in the country, legislation does not vest ownership of genetic resources in the state, unless they occur on state land. The landowner in South Africa, in terms of common law, owns both the biological and the genetic resources on or under his/her property.
Is access to genetic resources or	The Act outlines that the commercialisation phase of bioprospecting may only take place subject to the granting of a permit, which will only be granted if the interests are protected of: (i) Stakeholders which is providing or giving access

utilization of genetic resources defined? What activities are covered by ABS requirements?	to the indigenous biological resources to which the application relates; and (ii) an indigenous community or individuals: i. whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of proposed bioprospecting; or ii. whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting. The Act mandates that a permit applicant, must disclose all material information and obtain prior informed consent from the stakeholder providing or giving access to the indigenous biological resource (bullet a above) by entering into; (a) a material transfer agreement (MTA) that regulates the provision of or access to such resources; and (b) a benefit-sharing agreement (BSA) that provides for sharing by the stakeholder in any future benefits that may be derived from the bioprospecting. In the case of traditional use, knowledge or discoveries (bullet b above), the permit application must; a. disclose all material information and obtain prior consent of the indigenous community or individuals to use any of their traditional knowledge of or discoveries about the indigenous biological resources for the proposed bioprospecting; b. enter into a benefit-sharing agreement (BSA) that provides for sharing by the stakeholders in any future benefits that may be derived from the relevant bioprospecting. Benefit-sharing agreements must thus be entered into with both categories of stakeholders and, in addition, a material transfer agreement (MTA) must be entered into with stakeholders who give access to the indigenous biological resources. The Act also mandates inclusions required in both BSAs and MTAs in South Africa. If it has not been possible to conclude such agreements, a request for the intervention of The Minister for the purposes of negotiating such agreements is propable in accordance with Section 82 of the Act. Section 85 of the Act also outlines the setting up of a Bioprospecting Trust Fund into which benefit sharing agreement money would be deposited for payment to all appropriate beneficiaries. Finally, Chapter 7 of the Act outlines Permit processes for biodiversity in the country. Access and Benefit Sharing (ABS) legislation has thus been long in operation in the country, with the key objective of the fair and equitable sharing among stakeholders of benefits arising from bioprospecting involving any indigenous biological/genetic resource and/or associated Traditional Knowledge.
How are indigenous and local communities and traditional	The BABS Regulations define indigenous community as any community of people living or having or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure and (a) whose traditional use of the biological resources to which an application for a permit relates, have initiated or will contribute to or form part of the proposed bioprospecting: or (b) whose knowledge or discoveries about the indigenous biological

knowledge defined?	resources to which an application for a permit relates are to be used for the proposed bioprospecting. This is further pronounced in the Protection, Promotion, development and management of indigenous knowledge systems Bill, as indigenous communities are defined as communities in the Republic of South Africa who are regarded as African on account of their descent from population which inhabited the Republic or the geographical region to which the Republic belonged, at the time of colonisation and who irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions, including the African human population in a distinct geographical area, with ownership over its indigenous knowledge governed partially or completely by its own customs, traditions or laws. Traditional use or knowledge as stipulated in the BABS Regulations refers to the customary utilisation or knowledge of indigenous biological resources by an indigenous community, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised by them, an includes discoveries about the relevant indigenous biological resources by that community.
Who owns traditional knowledge? How is traditional knowledge found in the public domain (e.g. publications) addressed?	Indigenous knowledge holders and indigenous knowledge practitioners are the custodians of the indigenous resources in accordance with customary law and practices of their particular community or indigenous community, as individuals, families or societal group representative of the particular community. Traditional Knowledge is found in the public domain in various ways. People can be made aware via books, articles, media or interactions with community members or sometimes the knowledge is commonly known or widely shared among a number of indigenous communities and is therefore in the public domain. However in these cases indigenous communities still have rights over the traditional knowledge because there is common understanding that a specific community discovered or developed this knowledge. On the other end, SA through its Department of Science and Technology has developed the National Recordal System which records and documents indigenous knowledge of indigenous and local communities associated with indigenous biological resources.
What types of measures were adopted and implemented: Policy, legislation,	South Africa has legitimised environmental policy principles through the promulgations of a suite of environmental legislation between 1998 and 2004. The National Environmental Management Act, 1998 (Act No. 107 of 1998) (NEMA) is categorised as the framework legislation as it defines the overarching and generic principles in which environmental legislation in South Africa is embedded. The overarching objective of the Act is to provide legal effect to the

regulations?	environmental rights enshrined in Section 24 of the Constitution of the country. The National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) (NEMBA), which legitimises the White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity, is the legislative instrument which governs the bioprospecting sector of the country. The Act effectively sets out South Africa's domestic objectives to address the Convention on Biological Diversity. The Bioprospecting, Access & Benefit Sharing (BABS) Regulations (No. R138 of 2008) came into force on 1 April 2008 with the purpose of regulating the bioprospecting through permit system in South Africa. These regulations further set out the contents of, the requirements and criteria for benefit-sharing and material transfer agreements and also govern the discovery and/or commercialisation phase of a bioprospecting project and the export of any IBR from South Africa for the purpose of bioprospecting or any other kind of research. They prescribed the following forms: permit application (Annexure 2 & 3); permits (Annexure 4, 5 & 6); MTA (Annexure 7) and BSA (Annexure 8); and Notification form. The Department of Science and Technology (DST) has a policy on indigenous knowledge system. DST has also developed the Bill on the Protection, promotion, development and management of indigenous knowledge systems and also established a National Recordal System. The Department of Trade and Industry (DTI) has subsequently published the Patents Amendment Act of 2005, which legitimises the gaps in IKS protection highlighted in the IKS policy of 2004. This amendment to the 1974 Patent Act has the key purpose to mandate that an applicant for any patent furnish information on the role played by any indigenous biological resource, an indigenous genetic resource or traditional knowledge or use in an invention. In addition, The Intellectual Property Laws Amendment Bill was introduced in 2011, to in part, provide recognition and afford protection to indigenous knowledge held by indigenous communities.
How were national users of genetic resources considered (e.g. research institutes, universities)?	The Department of Environmental Affairs has conducted several workshops, seminars, conferences, media events and information sharing sessions throughout the country to raise awareness on Bioprospecting, Access and Benefit Sharing whereby all stakeholders inclusive of individuals, research institutions, associations, universities and companies have been invited to participate and engage in the process.

What is the procedure for PIC? What are the key conditions for obtaining PIC? Who may grant PIC for use of GR and TK?	Prior informed consent is considered to be an approval in advance for the use of biological resources and/or any associated traditional knowledge based on adequate information disclosure. A permit applicant is required to provide information as to what steps were taken in identifying the relevant stakeholders of which the permit issuing authority could also request expert advice which will enable it to determine whether the correct stakeholders have been identified and protected. The Biodiversity Act deals with PIC stating that prior to a permit being issued by the authority, the following must be in place; (i) all relevant material has been disclosed to stakeholders, including information about the intended end result (ii) the stakeholders have consented to providing access or sharing of knowledge (iii) material transfer and benefit sharing agreements have been concluded with those stakeholders and (iv) the agreements have been approved by the Minister who must be satisfied that BSAs are fair and equitable to all parties.
Is the procedure different when GR are accessed for basic research purposes or for commercialization purposes?	PIC procedures are different. Research other than commercialisation conducted in South Africa does not need a bioprospecting permit, but may need a collection and/or research permit from the relevant provincial authority. Research other than commercialisation to be conducted outside South Africa requires an export permit and applicable law is that of the Convention on International Trade in Endangered Species of wild fauna and flora (CITES) where applicable, Threatened or Protected Species (TOPS) where applicable, BABS Regulations and provincial ordinances, where applicable. Access to genetic resources for commercialisation purposes conducted outside South Africa will require an Integrated export and bioprospecting permit issued by the Minister. See Appendix 1
If a two phase approach is in place, providing PIC for research and requiring a new PIC for commercialisation? What is the trigger for the second phase? For example	In circumstances whereby a project will take a two phase approach, that is research (discovery) phase followed by the commercialisation phase, PIC is required for the research phase and new PIC must be obtained for commercialisation. It is important to note that benefits will be different at different phases of bioprospecting. PIC in the research phase will result in a MTA in place which may be renegotiated in the commercialisation phase which will result in a BSA in place. Triggers for commercialisation are defined in NEMBA and may include the following activities in relation to IBR; (a) commencing product development, including the conducting of market research and seeking pre- market approval for the sale of resulting products; (b) the multiplication of indigenous biological resources through cultivation, propagation, cloning or other means to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils; (c) trading in and exporting of indigenous

clinical trials, patenting?	biological resources to develop and produce products, such as drugs, industry enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils; (d) obtaining or transferring any intellectual property rights or other rights; (e) the filing of any complete intellectual property application, whether in South Africa or elsewhere; (f) commercial exploitation. See Appendix 1
Are there different PIC requirements for different types of genetic resources (e.g. marine, forest)?	Not explicitly. The Marine Living Resources Act (No. 18 of 1998) provides for the conservation of marine ecosystems, the sustainable use of marine living resources and for orderly and equitable access to such resources. ABS is not explicitly covered by the Act but existing recreational permits could allow sufficient quantities to be legally removed for analysis. Exemptions are granted for a number of activities, including research and could be used for bioprospecting purposes. The National Forests Act (No. 84 of 1998) purpose includes the sustainable use, management and development of forests, the restructuring of State forestry, the protection of certain forests and trees, community participation etc. Certain activities may be licensed in State forests including the collection of biological resources. However, in the case of bioprospecting activities, NEMBA and the BABS Regulations requirements prevail.
What is the average delay in obtaining PIC from the time access is officially requested?	Obtaining consent is not a quick, once-off process but rather iterative and progressive as it is about building relationships and trust between parties. Circumstances may differ from case to case which may impact on time taken to obtain PIC but principles of PIC are non-negotiable. In the case of issuance of permit, the average time frame is four months (N.B if permit application requirements are met), for the Competent National Authority to make a final decision. The BABS Regulations refer to time periods as a number of working days from Monday to Friday and excluding public holidays, first day not being accounted for but the last day being included.
Is PIC awarded for a particular period of time?	PIC is part of a process of building trust and developing relationships. It does not happen quickly. The relationships of trust are often built over a number of years. Negotiating the mutually agreed terms (MTA) of use of the information or resource will determine how PIC is granted. However, on issuance of bioprospecting permits, validity of the permit is stated and it range from 3 years to five years.

Is a permit issued when PIC is granted?	Yes, a permit with or without conditions may be granted by the Minister. The Minister has established a National Bioprospecting Advisory Committee, to provide technical input during the evaluation of permit applications and also make recommendations for the Minister to issue or reject the permit application. The Advisory Committee meets four times a year to review permit applications. Ad hoc meetings are also convened when necessary.
What is the procedure in place for the negotiation of MAT:	Mutually agreed terms is an agreement reached between the providers of the genetic resources and users of the resources on the conditions of access and use of the resources, and the benefits to be shared between both parties. A material transfer agreement and a benefit sharing agreement are required when access to indigenous biological resources is needed. These two agreements go hand-in-hand. If access to indigenous biological resources is required during the commercialisation phase of a project, a bioprospecting permit application is to be submitted to the Issuing Authority, which must be supported by a material transfer agreement (MTA). The MTA must be signed by the provider and the user of IBR. Certain information is to be provided by the user to the provider before an MTA is considered. In the event that the user wants to provide the IBR to a third party eg a research institution, the primary provider may set condition on such transfers to third parties ensuring that this is stated in the MTA, noting that the transfer to third parties is subject to written consent from the Minister. Provider of IBR is to furnish the user with adequate information in order for the user to be able to submit a permit application. An MTA and a BSA are required when the bioprospector needs access to IBR and TK meaning that you never have a MTA without the BSA. If provider has decided to give the bioprospector access to IBR and/or TK, the provider will also have to provide some information that the user will need in order to fill out the permit application and this information is given by the provider once he/she has decided to give access to the user to IBR and/or TK. BABS Regulations Annexure 7 and 8 provide templates for the kind of information that is required when concluding a MTA and BSA. Information required amongst others may include name and contact details and if applicable, the designation of the person signing the agreement. If provider agrees to share IBR and enter into a BSA with user, provider will have to complete a MTA. If provider has agreed to share TK and enter into a BSA with the bioprospector,

	the provider will have to share the knowledge and traditional use associated with the IBR. All information included in both agreements will be shared with the bioprospector, DEA as well as the DEA-appointed advisory committee in charge of analysing bioprospecting permits. If it is an indigenous community that is providing access to IBR or is sharing TK with the bioprospector, than representative will have to provide a description of the community, name and capacity of the individual representing the community in the negotiations and contact details of that representative. An indigenous community must adopt a resolution that confirms that the representative identified in the agreement has the authority to enter in to such agreements on behalf of the community and the resolution will have to state that the community is fully aware of the bioprospecting project and that it consents to the BSA. The provider has to decide and agree with the user on the type of benefits that he/she/they would like to receive as part of the BSA and a decision must be taken jointly with the users on how often the BSA is to be reviewed with a view to amend the agreement where necessary. One month before the review, the bioprospector is to submit to the provider any new material information about the bioprospecting so as to allow the provider time to familiarise themselves with the material before the review. Entering into a BSA with one bioprospector does not prevent the provider from entering into BSAs with other users unless this is specified in the agreement.
Are MAT a condition for obtaining PIC?	Before access to IBR or traditional knowledge can commence, the PIC from owners of the IBR or TK holders is required. The user is expected to fully disclose the intended use of the resource, the method of collection and the intended outcome of the research. All this will be based on Mutually Agreed Terms which is a condition for obtaining PIC. MAT serve as evidence for granting of PIC by the relevant stakeholder. The MATs are negotiated by both parties and stipulated in the MTA and BSA for approval by the Minister.
Are key elements of MAT set out (content	Standard forms for Material Transfer Agreements and Benefit Sharing Agreements are provided in Annexures to the BABS Regulations. This standard format must be used and additional terms and conditions can be included in the

requirements)? Is a template for MAT available?	standard form agreement as an annexure if necessary. Mutually Agreed Terms is thus incorporated into both the MTA and BSA, and not stipulated in a separate document.
Are specific requirements in place for the sharing of monetary and non-monetary benefits?	The Biodiversity Act stipulates that government must establish a Bioprospecting Trust Fund into which all monies arising from BSAs must be paid into and the Director General of the Department of Environmental Affairs is responsible for administering the fund. The Fund is managed in accordance with Treasury Regulations in terms of the Public Finance Management Act, 1999 (Act No.1 of 1999). Money received by the fund is paid out annually to the beneficiaries unless the BSA stipulates a different time period for making out payments. Monetary payments do not go directly to the providers/ community from the users but through the Fund. It is being emphasized that the Bioprospecting Trust Fund is very different from a Community Trust Fund that may be established to distribute benefits at community level. Non-monetary benefits may come in many different forms and the Department of Environmental Affairs is available to assist beneficiaries in monitoring the administration of such benefits at community/provider level.
What types of compliance measures are in place in order to ensure that users respect ABS requirements in the country?	The National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) (NEMBA), which legitimises the White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity, is the legislative instrument which governs the bioprospecting sector of the country. The Bioprospecting, Access & Benefit Sharing (BABS) Regulations (No. R138 of 2008) came into force on 1 April 2008 with the purpose of regulating the bioprospecting permit system in South Africa. The Regulations stipulate that the permit holder on an annual basis, submit a status report to the Minister in a format determined by the Minister. It is also imperative to clearly state that in any agreement how disputes between provider and user will be resolved; mediation prior to arbitration is considered a better option. Costs of mitigating or remedying the impact of the bioprospecting on the environment will be for the permit holder. It is an offence if a non-permit holder; (a) (i)undertakes bioprospecting involving indigenous biological resources, (ii) exports from the Republic of South Africa any indigenous biological resources for the purpose of bioprospecting or any other research, (b) performs the activity for which the permit was issued otherwise than in accordance with any conditions subject to which a permit was issued, (c) permits or allow any other person to, or to omit or to do anything which is an offence in terms of the BABS Regulations. A person convicted could be liable to jail time, a fine or both. The fine is up to 10 million ZAR and imprisonment not exceeding 10 years or three times the

	commercial value of the activity. In addition failure to notify the Minister about the discovery phase of bioprospecting project is also an offence liable to the penalties as stated above.
Who are relevant stakeholders at the national level (e.g. research community, universities, ex situ collections, indigenous and local communities, private land owners)?	All of the examples stated are relevant stakeholders.
What is the mechanism of implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)?	SA is not Party to the ITPGRFA. There is no mechanism of implementation set out.
What is its relationship with the ABS framework?	The main component of the ITPGRFA is the Multilateral System (MLS). In this context, GR on the Annex 1 List of species currently 81 forage species from 29 genera and an undefined number of crop species from 51 genera, (covering the vast majority of plant crops consumed by humans) - are freely available to plant breeders, farmers, scientists etc. However

puts in place measures to ensure recipients share benefits they derive from the use of genetic materials with the countries where they originated.

Those who access genetic materials through the system are required not to claim any rights that "limit the facilitated access to the PGRFA, or their genetic parts or components, in the form received" (Article 12.3(d)). If plant genetic resources accessed from the MLS are commercialized, the recipient "shall pay an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment" (Article 13.2(d)(ii)). A pre-fixed percentage of the benefits from commercialization flow into a common fund that is used to support future research, breeding and training projects. The system is operationalised through the standard MTA.

In the context of the ABS and TK, farmers' rights as codified in the ITPGRFA deal with benefit sharing but not with access aspects. During the ITPGRFA negotiations it was argued by some parties that farmers' rights should also cover free access to and exchange of IP-protected plant material as acknowledgement of farmers' contribution to the creation of the existing diversity of plant genetic material without which modern plant breeding could not exist. Such interference with the IP system was not accepted by countries with strong plant breeder interests. The ITPGRFA finally was equipped with a provision in Article 9.3 that the national implementation of farmers' rights shall not "limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate." The only international treaty that provides for such rights, though only on a voluntary basis, is the UPOV Convention.

Negotiated post-Rio, a conscious effort was made to ensure that the ITPGRFA is fully consistent with the provisions of the CBD. A provision that is of relevance in the ABS context can be found in Article 12.3(h) which says that "[w]ithout

	prejudice to the other provisions under this Article, the Contracting Parties agree that access to plant genetic resources for food and agriculture found in in situ conditions will be provided according to national legislation or, in the absence of such legislation, in accordance with such standards as may be set by the Governing Body." According to the definition of "in situ" given by the ITPGRFA as well as by the CBD, this case would cover those plant genetic resources in natural surroundings as well as on farmers' fields if they have "developed their distinctive properties" in these locations. In 2010, the ad hoc Advisory Technical Committee on the Standard Material Transfer Agreement and the Multilateral System of the ITPGRFA started its work on compiling information and views on such standards. The 4th and 5th Session of the Governing Body in March 2011 and September 2013 respectively did not further elaborate on the work towards access standards for in situ conditions. The Nagoya Protocol (NP), having been negotiated after the ITPGRFA, has a provision that ensures that the latter treaty (and not the NP/CBD) governs plant genetic resources for food and agriculture covered by the ITPGRFA for those countries that have ratified it. Under Article 4(4) of the NP, "[w]here a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument", except, as stipulated in Article 4(1) of the NP, "where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."
How are the crops listed in Annex 1 of the ITPGRFA treated in the national ABS	The Annex 1 crops are currently excluded from the national ABS framework. A special situation may exist, however, for countries that have not, to date, become party to the ITPGRFA. Since South Africa is a party to the CBD and the NP, South Africa would be bound by the ABS provisions in the CBD over plant genetic resources, and the provisions of the NP. As the ITPGRFA is consistent with the CBD, there is nothing preventing the use of the ITPGRFA MTA for transfer of

framework?	plant genetic resources for food and agriculture to a non-signatory.
3. PROVIDERS OF GENETIC RESOURCES	
Where are GR mostly being accessed in the country (where is the greatest demand for access to GR)? In forest areas, marine areas, other?	South African law has a very wide definition which defines 'indigenous biological resource' (IBR) to include any living or dead organism of an indigenous species, any genetic material or derivatives of such organisms, or any chemical compounds and products obtained through use of biotechnology that have been altered with genetic material or chemical compounds found in indigenous species. It excludes genetic material of human origin, any exotic animals, plants or other organisms and indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture. In relation to the permit system that keeps records of all permits approved and granted, the greatest demand for access to GR is in plant material both wild harvested and cultivated.
Do foreigners carry out bioprospection in the country or do they access genetic resources from intermediaries (e.g. ex situ collections, universities or national research institutes)? In other words are GR accessed in situ or ex situ by foreigners?	Foreign individuals and entities are expected to apply jointly with South African Individuals or Universities and Research institutes for bioprospecting or export permits, and in most cases, genetic resources are accessed from ex situ collections. In terms of the Act, a permit may only be issued to; (a) a juristic person registered in terms of the South African Law, (b) a natural person who is a South African citizen or a permanent resident of South Africa, (c) a juristic person that is not registered in terms of the South African law or a natural person who is not a South African citizen or a permanent resident of South Africa, if that juristic person or foreign national applies jointly with a juristic or natural person referred to above. The majority of foreigners access genetic resources from ex-situ collections through collaboration will local institutions.
Do intermediaries play an important role for ABS in the	Intermediaries like universities and research institutions play an important role in ABS in South Africa as they are actively involved in the bioprospecting sector through conducting extensive research work possibly partnering with both local and foreign institutions and local communities and or individuals. They may also form joint ventures with

country (e.g. universities, research institutes, ex situ collections)	international organisations for reasons stated above and other reasons that may benefit the society of South Africa. In addition, intermediaries such as biotraders, play an important role in facilitating access to South Africa's raw materials of indigenous biological resources for further research and development in foreign countries.
Who are the main providers of GR accessed in situ in the country: the State? Private landowners? Indigenous and local communities?	South Africa provides genetic resources and these are often sourced from biotraders and also directly from indigenous and local communities. As stated above, despite the State being the trustee of biological diversity in the country, legislation does not vest ownership of genetic resources in the state, unless they occur on state land. The landowner in South Africa, in terms of common law, owns both the biological and the genetic resources on or under his/her property. Therefore, genetic resources are accesses mainly from private and communal land.
4. USERS OF GENETIC RESOURCES:	
Who are the main users of genetic resources in the country? The research community, the private sector? For what purpose do they access GR, (e.g. basic research, commercialization)? Are they mostly foreigners or nationals?	Both the research community and private sector are users of genetic resources. In accordance with the records in the permit system, Seventeen (17) permits granted are for commercialisation projects and these comprise of sixteen (16) local companies and one (1) foreign entity. Since the implementation of BABS Regulations, the Department of Environmental Affairs has received in total seventy seven (77) permit applications for commercialisation phase of bioprospecting of which sixty (60) are in the review and approval phase. DEA has received eighty one (81) notifications for the discovery phase. It must be noted that the Biodiversity Act distinguishes between the discovery phase and the commercialisation phase of bioprospecting. The discovery phase is when the user is trying to find out if there is any potential in the IBR that could further be developed into a commercial product and the commercialisation phase is when something with commercial potential has already been identified in the IBR.
If GR are accessed	There has been a surge in the use of natural products in industries such as cosmetics, nutraceuticals, pharmaceutical

for commercial purposes, what types of sectors are interested in these GR (e.g. pharma, cosmetics, agriculture, industrial biotech)?	and biotraders and genetic resources are utilised for both research and commercialization purposes. Of the seventeen (17) approved bioprospecting permits, nine (9) are Biotraders, two (2) are Pharmaceutical, one (1) is Cosmetic, one (1) Nutraceutical, one (1) Agricultural (Herbicides) and a Pharmaceutical, one (1) Insect repellent, one (1) Cosmetic and Biotrader and one (1) Pharmaceutical and Biotrader. Of the permit applications pending approval, thirty (30) are Pharmaceutical, fourteen (14) Biotraders, two (2) Nutraceutical and twelve (12) Cosmetic Companies.
Does the national ABS system in place also address the obligation of your country as user of genetic resources accessed in foreign countries? In other words, are obligations imposed on users in your jurisdiction who have accessed GR in foreign countries to respect ABS requirements of foreign countries?	Chapter 6 and 7 of NEMBA provides a framework for regulating bioprospecting involving indigenous biological resources and/or associated traditional knowledge. The BABS Regulations provide details on the processed and procedures for engaging in bioprospecting activities legally. A host of other laws, administered by other departments also have relevance in the effective implementation of the provision of NEMBA and BABS Regulations. As part of a preparatory process for the national implementation of the Nagoya Protocol on ABS, South Africa is continuously engaging with relevant stakeholders in particular on the new obligations outlined in the Nagoya Protocol on ABS which are not covered in the existing national legislation but requires administrative systems to be put in place for effective implementation thereof. South Africa being both a provider and a user has embarked on a national stakeholder engagement process to address the identified new obligations of the Nagoya Protocol being; (a) Article 15: Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit Sharing of the provider country and, (b) Article 17: Monitoring the Utilization of Genetic Resources. Concomitant to that is the review of the applicable legislation which will incorporate all the obligations emanating from the Nagoya Protocol.
5. ABS AGREEMENTS	
How many ABS agreements have	Since ABS agreements in South Africa are an inherent requirement of the bioprospecting permitting processes in the country, there are currently 17 permits issued, 72 MTAs and 32 BSAs approved by the Minister of Water and

been concluded? Is this information recorded? If not, please provide an indication.	Environmental Affairs and all these are kept on record by the national Department of Environmental Affairs.
Were these ABS agreements for non-commercial or commercial utilization of GR?	All the approved agreements are for the commercialisation phase of bioprospecting.
Were any benefits derived from these agreements?	Yes, both monetary and non-monetary benefits have been derived from these agreements. Examples are given below.
What are the types of benefits generated from these ABS agreements? Monetary, non-monetary? How are they shared? What type of support, if any, is provided to beneficiaries receiving benefits arising from MAT and ABS agreements?	The types of benefits generated from ABS agreements tend to vary from case to case and are divided into two categories; monetary and non-monetary benefits. These could either be short term, medium term and long term as stipulated in the BABS Regulatory Framework. There are many benefits available to providers to choose from depending on whether the stakeholder is providing access to the indigenous biological resources or is an indigenous community and none of them are exclusive. BABS Regulations provides a list of benefits that are more relevant if the stakeholder to the agreement is providing or giving access to the indigenous biological resources and a second list provided is more relevant to if a stakeholder to the agreement is an indigenous community. Monetary benefits as stated above are dealt with through a Bioprospecting Trust Fund and inclusive of non-monetary benefits, the Department of Environmental Affairs plays a support role to beneficiaries through monitoring of compliance to agreements by the users.

Examples of implemented ABS agreements	**1. HGH PHARMACEUTICALS (PTY) LTD (2009)** **Type of permit:** Integrated export and Bioprospecting permit **Bioprospecting Project on *Sceletium tortosium*** The Minister of Water and Environmental Affairs issued an Integrated Export and Bioprospecting permit to HGH Pharmaceuticals (Pty) Ltd for local and international research on cultivated plant material and extracts from *Sceletium tortosium*, commonly referred to as Kanna, Channa or Kougoedand to commercialise the product. The product is commercially available in South Africa as Zembrin. Beneficiaries: South African National San Council (San), Paulshoek and Nourivier (Nama) communities **BENEFITIATION** **Monetary:** • HGH Pharmaceuticals will pay the South African San Council an annual royalty of 5% per annum on the net proceeds they receive- for the first three years royalty will only be payable in respect of net proceeds received during each year in excess of R5million • 50% of royalties received by San will be paid to the Paulshoek and Nourivier communities • Annual payment of 1% per annum on net proceeds of sales received for exclusive use of the San Logo • Upfront payment was paid into the Bioprospecting Trust fund of the San Council and the communities of Paulshoek and Nourivier **Non-monetary:** • The bioprospecting project continues to contribute to the enhancement of scientific knowledge of researchers employed at the South African consortium, HGH Pharmaceuticals • Acknowledgement is given to the San community who are the indigenous knowledge holders through the endorsement of their logo on the product

- Job creation from the cultivation of the indigenous biological resource

2. EDAKENI MUTHI FUTHI TRUST (2011)

Type of Permit: Bioprospecting permit

MUTHI FUTHI TRUST PROJECT

The Minister of Water and Environmental Affairs has awarded a bioprospecting permit to Edakeni Muthi Futhi Trust for the cultivation, processing and marketing of herbal products containing active ingredients from seventy eight 78 indigenous biological resources.

Beneficiaries: Edakeni Community, Senzokuhle Food Production Cooperative Ltd and Enzangakho Consultancy cc

BENEFITIATION

Monetary:

- The community has a share of up to 50% of any profits generated by the business into the Trust

Non-monetary:

- Sustainable employment for up to 40 rural women
- Equipment and infrastructure support to the community
- Environmental and conservation education
- Training on agro-processing

3. COUNCIL FOR SCIENTIFIC AND INDUSTRIAL RESEARCH (CSIR)

Type of Permit: Bioprospecting permit

***LIPPIA JAVANICA* PROJECT**

The Minister of Water and Environmental Affairs issued a bioprospecting permit for the cultivation of *Lippia javanica*, the distillation and extraction of the oil for commercial production of mosquito repellent candles.

Beneficiaries: National Traditional Healers Committee

BENEFICIATION

Non-monetary; Monetary and "in kind" benefits:

- This is a community owned enterprise project at the cultivation site
- 8% of the milestone payment on all the income received from license
- Employments of Giyani community (27 members of the Maswangani and Mabunda communities) members at Giyani Facility in the cultivation, harvest, distil oils and manufacture mosquito repellent candles.
- Technology transfer

4. ECOPRODUCTS

Type of permit: Integrated export and Bioprospecting permit

Bioprospecting Project on *Adansonia digitata*
The Minister of Water and Environmental Affairs issued an integrated export and bioprospecting permit to EcoProducts.

Project title: The main purpose of the project is to buy, produce and sell baobab seed and fruit powder to be used as food and cosmetic ingredients**.**

	Beneficiaries: Beneficiary to the project is the Mukovhawabale and Muswodi Dipeni Communities, represented by Chief Lingani Kenneth Nethengwe and Chief Mikosi Emmanuel Nefolovhodwe respectively in Venda, Limpopo Province who are involved in collecting Boabab fruits. **BENEFITIATION** **Monetary:** • Reimbursement per kilogram of boabab fruit on delivery as upfront payment delivered by the communities to EcoProducts; **Non-monetary** • The livelihoods of over 1500 marginalised rural women would be supported; • On-going communication with the communities; • Up to 15 people would be permanently employed; • Upgrading and processing of local processing facility; • Establishment of local nursery for growing baobab trees; • Simplified and popularised posters, manuals, pamphlets and other document translated into local languages; • Inclusion of local communities in the research programmes and projects; • Recognition and promotion of traditional knowledge; • Long-term research into the effect of environmental change on Baobab survival and recruitment; and • Development of materials for Baobab environmental education for schools, communities and Other implemented ABS examples can be found on the DEA website following the link below. www.environment.gov.za/sites/default/files/docs/permits_awarded.pdf
Have these ABS agreements contributed to conservation and	Conservation benefits are imperative in order to support the ecosystem from where the resource was extracted in order to avoid over exploitation and unsustainable use of the resource. An example of notable benefits that have been included in some of the agreements included but not limited to;

sustainable use of biological diversity in your country?	• Genetic information generated through this project will contribute to South African conservation objectives including the prevention of gene pollution • Support for conservation through bursaries • Training on sustainable harvesting methods of the resource • Environmental education • Environmental and conservation education • Resource Assessment and regulated quantity of authorised indigenous biological resources for wild collection/ harvesting • Biodiversity Management Plan for Species It is imperative that the permit issuing authorities ensure that the relevant activity will not deplete an indigenous biological resource beyond a level where its integrity is jeopardised and that the impact of the activity will be negligible or will be minimised and remedied, thus inclusion of conservation benefits in all agreements.
6. KEY LESSONS LEARNED	
What will you do differently in future?	Continuous improvement requires a commitment to doing things differently. We are learning from past experiences and building on successes that we have achieved. Challenges (as listed below) that have been encountered are being prioritised and addressed to ensure that a functional and seamless ABS system is attained.
Based on your experience, what are key elements for a functional ABS system?	As stipulated in NEMBA, key elements of a functional ABS system must ensure the following; (a) bioprospecting involving indigenous genetic and biological resources is regulated; (b) the exports from the South Africa of indigenous genetic and biological resources for the purpose of bioprospecting or any other kind of research are regulated; (c) a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous genetic and biological resources is provided for and; (d) that the nation's indigenous genetic and biological resources are developed and utilized in an ecologically sustainable manner while promoting social and economic development, in particular in the areas where the indigenous genetic or biological resources and associated traditional knowledge is accessed. This

	entails the following; • Anyone carrying out bioprospecting involving IBR and if applicable associated traditional use or knowledge must have a permit obtained from a relevant issuing authority • Anyone exporting IBR for the purposes of bioprospecting or other research must obtain a permit obtained from a relevant issuing authority • No person may, without first notifying the Minister, engage in the discovery phase of bioprospecting involving any indigenous biological resources. • Correct stakeholders in a benefit sharing agreement are identified • Before a permit is issued, any interests of stakeholders are protected • MTAs and BSAs are in a prescribed format and entered into by all parties involved • A mechanism to monitor compliance to agreements is in place • A Bioprospecting Trust Fund is established into which all moneys arising from BSAs and due to stakeholders must be paid into
In relation to procedures for PIC	• Identifying the correct community to seek PIC from is of paramount importance during the initial stages • It must be ensured that all relevant material has been disclosed to stakeholders including information about the intended use, end result and method of collection • The stakeholders must agree to providing access to IBR or sharing of TK prior to any further engagements on the intended venture • All agreements must be confirmed and documented with issues related to access to IBR/Traditional Knowledge
In relation to the negotiation of MTA	• MTA must be finalised prior to submitting a bioprospecting permit application to the Competent National Authority • MTA must be signed by both the provider and user of the IBR and/or traditional knowledge • If user is to provide IBR and/or traditional knowledge to a third party, provider must set conditions on such transfer and it must be stated in the MTA and the Competent National Authority must be notified • Provider must provide relevant information to the user that will be needed to complete the application form • Standard format for drafting of MTA must be made available to provider and user

	• The Minister to approve all MTAs or amendments to such agreements.
In relation to the sharing and distribution of benefits	• There should be an agreement that outlines how the benefits arising out of a bioprospecting project will be shared between the provider and the user • Provider should provide information to user that will be required in order to fill out permit application • Information required for the agreement is partially similar as that needed for MTA • The BSA must include period of review • The Minister approves all BSAs or amendments to such agreements.
In relation to compliance	• A clear indication of what constitutes an offence • A clear indication of what penalties are in place if user is convicted • User to report back to the Minister on an annual basis on project progress
Based on your experience, what were key challenges faced with implementation?	Appropriate ways to identify and verify holders of traditional knowledge to seek PIC and negotiate mutually agreed terms remain unclear in the concepts and terms used in ABS measures. For example, a wide variety of terms and definitions are used by different sectors to describe holders of traditional knowledge associated with genetic or biological resources and related products, and often the same language may be used by two parties to describe two different situations. Other challenges include • Identification and protection of stakeholders; • Access to the IBR and verification of traditional knowledge owners; • Collection, use, propagation, cultivation or trade of IBR for domestic or subsistence purposes; • Regulation of the various Muthi markets, and • Lack of uniform systems applied to different sectors involved in bioprospecting and biotrade The uptake of the permitting and the underlying ABS requirements has been slow in the country. Current indications are that less than 300 species have been requested in the permit application procedure (note this does not imply 300 permits have been submitted as one permit request may include application of a number of species) and only 17 permits have been approved by the Minister of Water and Environmental Affairs. The slow uptake of the permitting procedure is due to a number of constraints being experienced by the bioprospecting sector, including: • Despite a set of guidelines for the process, the quality of permit application documentation received by DEA is poor,

	which delays the processing of the permit applications • Lack of National System for the verification of legitimate traditional knowledge owners/holders • Lack of accurate data on the amount of raw materials exported out of South Africa, whether legal or illegal and the amount of revenue generated by Biotraders is unknown • Universally accepted means of implementing intellectual property recognition is yet to be formulated • Lack of human resource capacity • Some negotiations of BSAs are not conducted on equal footing • Foreign and local companies conducting unauthorized bioprospecting. More efforts required in establishing national system to monitor and track the movement of IBRs to national and foreign R&D companies for commercial products development.
In terms of process , procedures established and content (e.g. to gather support for the system at the national level, by various stakeholders, i.e. what were key messages conveyed by stakeholders regarding the implementation of the system?	Several workshops, seminars, conferences and information sharing sessions are continuously conducted with stakeholders throughout the year in order to raise awareness on Bioprospecting, Access and Benefit Sharing. Unanimously, stakeholders have in principle agreed and accepted the ABS system. Comments that have been conveyed regarding the system are; • Processing time for approval of permits is too long and is having a negative effect on their businesses • Application forms for permits are not user friendly • Permit fee structure should be categorised instead of the current standard-fee application for all • Regulations must be specific in content. • It is a system that will ensure fair and equitable share of benefits amongst stakeholders
Other relevant issues	In ensuring an effective and seamless ABS system in place, DEA has implemented the following measures amongst other initiatives;

	• Translated the BABS Regulations and BABS Guidelines into all (eleven) SA official languages • Established an information portal housed within the DEA website serving as the National ABS Clearing House Mechanism • Publishing of guidelines entitled *"SA's Bioprospecting, Access and Benefit Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators".* • *Publishing of BABS Posters, Pamphlets and Frequently Asked Questions Booklets* • Developed animated video clip to relay in a simple and appealing way the ABS system to stakeholders and the general public • Several workshops, seminars, conference, media events and information sharing session are conducted annually to • raise awareness on Bioprospecting, Access and Benefit Sharing.

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16) Constitution of the Republic of South Africa, 1996 (Act No. 108 of 1996)

8. APPENDIX 1: PROCESS FLOW DIAGRAMS

The flowchart below sets out a step-by-step guide for the ABS process for providers of IBR and TK.

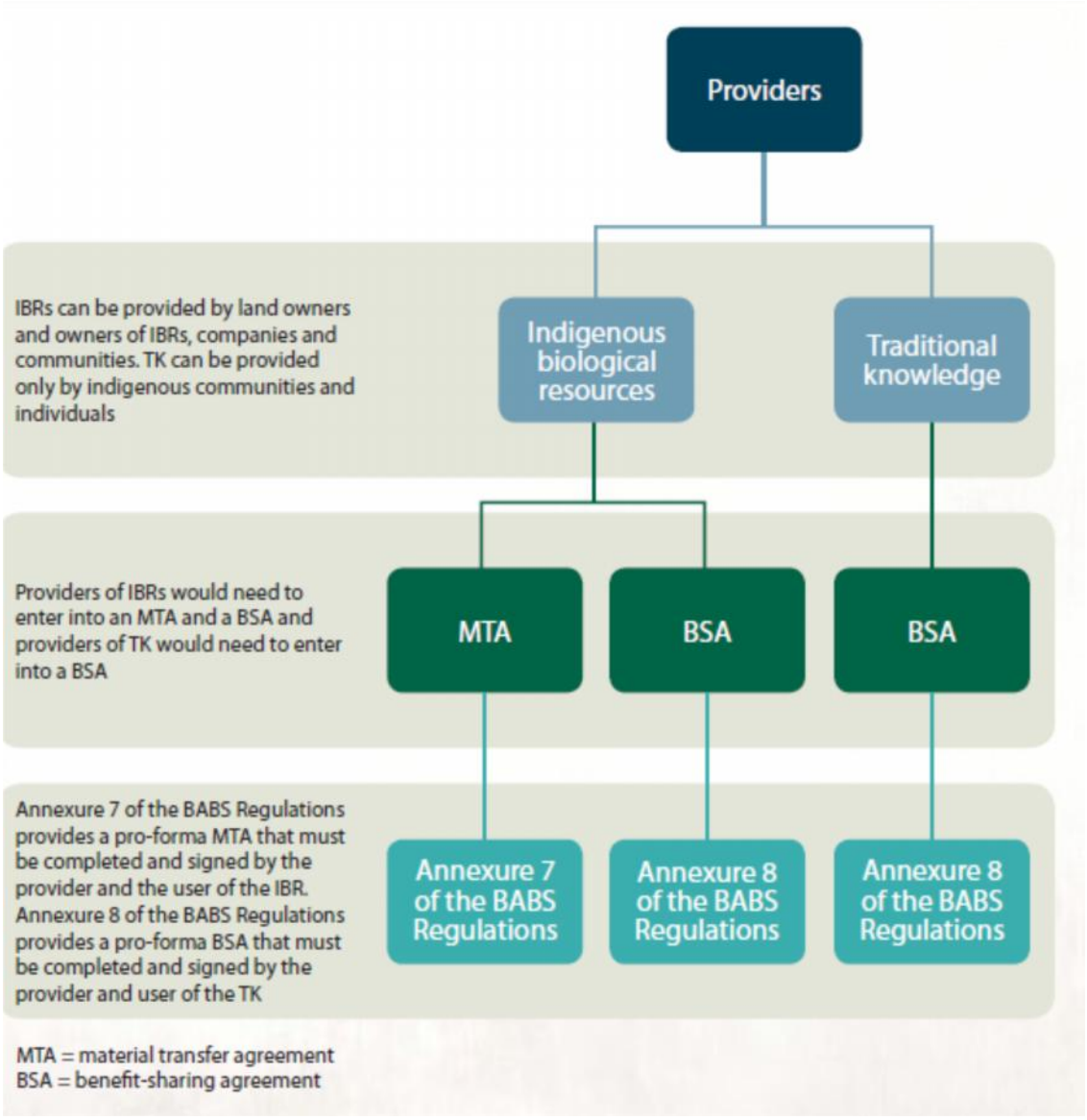

Figure 1: Access and Benefit Sharing Process Flow Chart (taken from DEA, 2012).

The flowchart below sets out a step-by-step guide on the Bioprospecting, Access and Benefit Sharing Process overview.

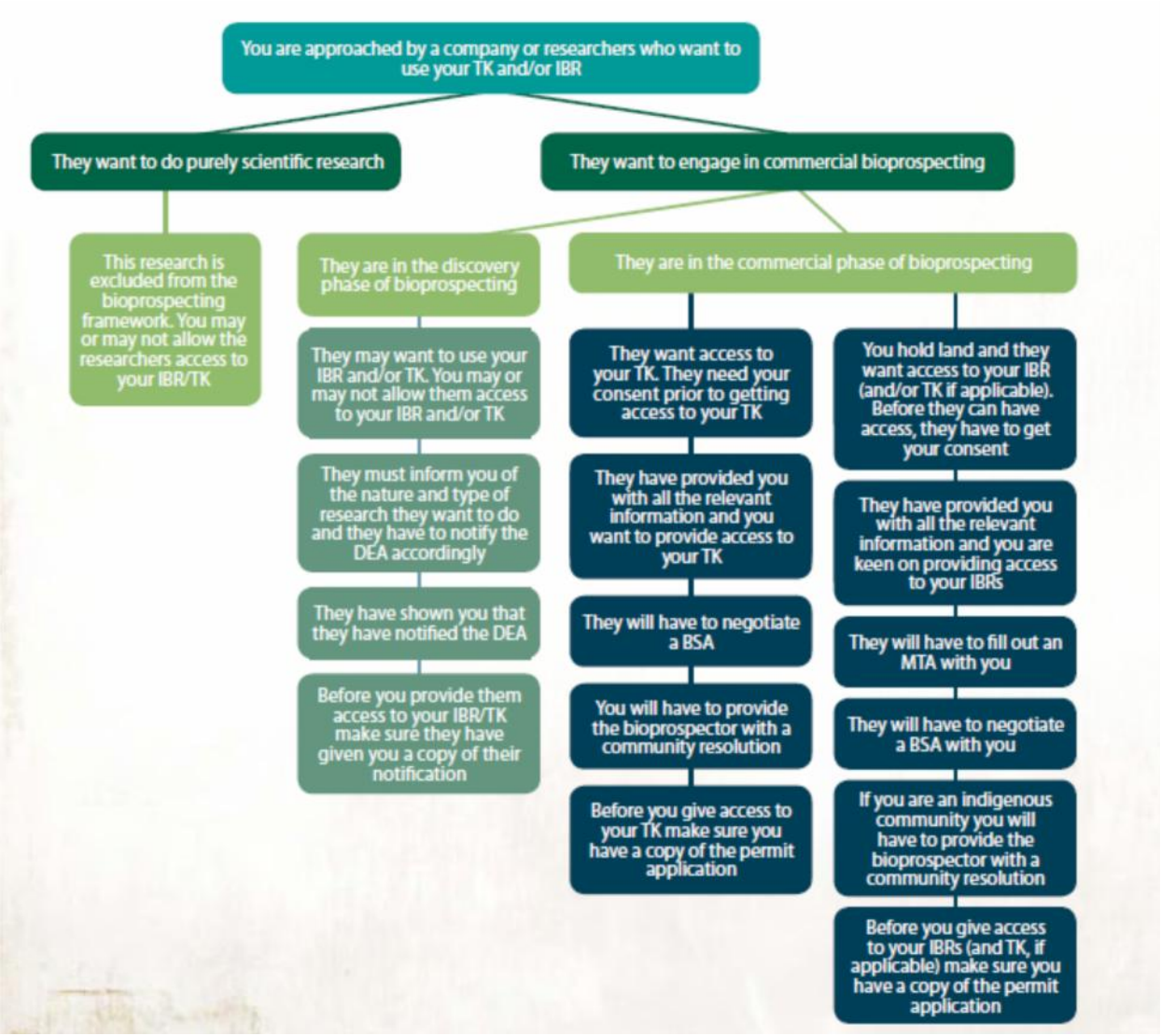

Figure 2: Bioprospecting, Access and Benefit Sharing Process overview. (taken from DEA, 2012).

The process for the application process for a permit in the commercialisation phase of bioprospecting is shown in Figure 3 below.

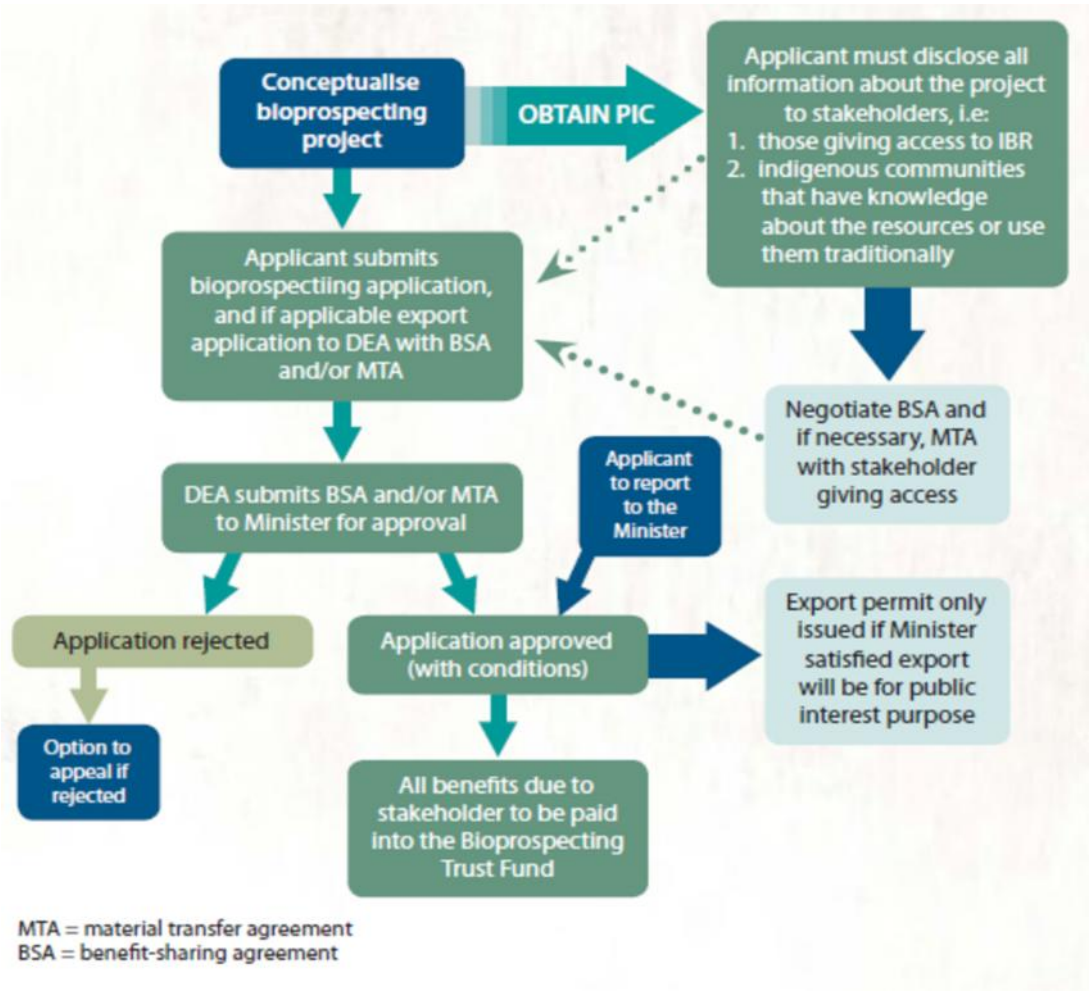

Figure 3: Process for the application process for a permit in the commercialisation phase of bioprospecting (taken from DEA, 2012).

Figure 4 below shows the bioprospecting permit requirements along the value chain.

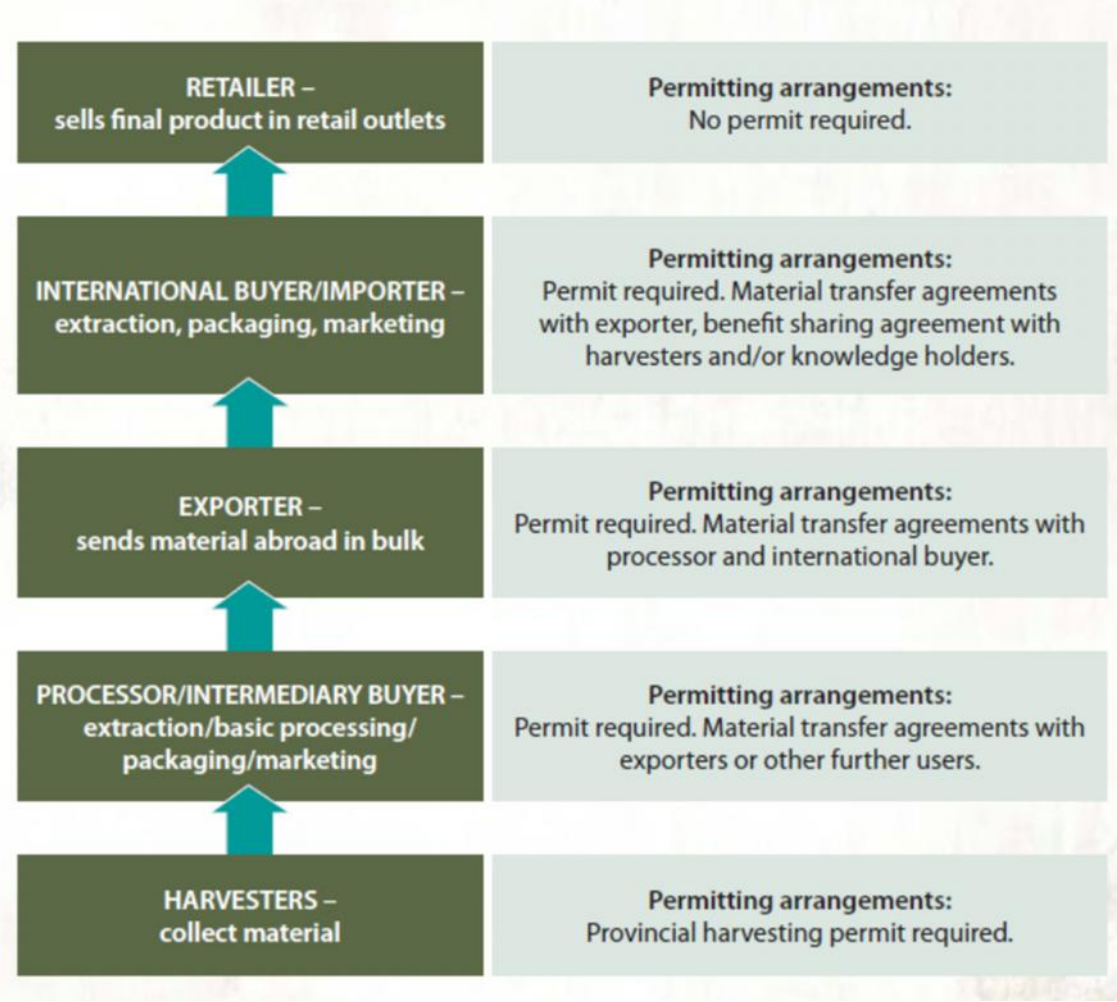

Figure 4: Bioprospecting value chain permitting requirements (taken from DEA, 2012)

9. APPENDIX 2: EXPLANATORY NOTE

The Intellectual Property Law Amendment Bill (2011) defined indigenous cultural expressions or knowledge means any form, tangible or intangible, or a combination thereof, in which traditional culture and knowledge are embodied, passed on between generations, and tangible or intangible forms of creativity of indigenous communities, including, but not limited to—

(a) phonetic or verbal expressions, such as stories, epics, legends, poetry, riddles and other narratives, words, signs, names or symbols;

(b) musical or sound expressions, such as songs, rhythms, or instrumental music, the sounds which are the expression of rituals;

(c) expressions by action, such as dances, plays, ceremonies, rituals, expressions of spirituality or religion, sports, traditional games, puppet performances, and other performances, whether fixed or unfixed; or

(d) tangible expressions, such as material expressions of art, handicrafts, architecture, or tangible spiritual forms, or expressions of sacred places;

Bioprospecting is defined in NEM: BA (2004) and the 2013 Amendment to the Act in relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes-

(a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application;

(b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities;

(c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation; or

(d) Trading in and exporting of indigenous biological resources in order to develop and produce products such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, extracts and essential oils

Biological diversity or ***biodiversity*** is defined in NEM: BA (2004) as the variability among living organisms from all sources including, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part and also includes diversity within species, between species, and of ecosystems;

Indigenous biological resources are defined in NEM: BA (a) when used in relation to bioprospecting, means any indigenous biological resource as defined in section 80(2); or (b) when used in relation to any other matter, means any resource consisting of-

(i) any living or dead animal, plant or other organism of an indigenous

(ii) any derivative of such animal, plant or other organism; or

(iii) any genetic material of such animal, plant or other organism;

(b) excludes- (i) genetic material of human origin; (ii) any exotic animals, plants or other organisms, other than exotic animals, (iii) indigenous biological resources listed in terms of the International Treaty plants or other organisms referred to in paragraph (u,)(iii); and on Plant Genetic Resources for Food and Agriculture.

Commercialisation is defined in NEM: BA (2004) and the 2013 Amendment to the Act in relation to indigenous biological resources relates to the following activities:

(a) Filing of a complete intellectual property application, whether in South Africa or anywhere else;

(b) Obtaining or transferring any intellectual property right or any other right;

(c) Commencing product development, including the conducting of market research and seeking pre-market approval for the sale of resulting products;

(d) The multiplication of indigenous biological resources through cultivation, propagation, cloning or other means to product and develop products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, extracts and essential oils.
(e) Trading in and exporting of indigenous biological resources to develop and produce products such as as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, extracts and essential oils;
(f) Commercial exploitation

Indigenous community according to the Intellectual Property Law Amendment Bill (2011) means any recognisable community of people originated in or historically settled in a geographic area or areas located within the borders of the Republic, as such borders existed at the date of commencement of the Intellectual Property Laws Amendment Bill, 2011, characterised by social, cultural and economic conditions which distinguish them from other sections of the national community, and who identify themselves and are recognised by other groups as a distinct collective.

Traditional use or ***knowledge*** according to BABS Regulations refers to the customary utilisation or knowledge of indigenous resources by an indigenous community, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised by them, and includes discoveries about the relevant indigenous resources by the community.

Stakeholders in NEMBA:
(a) A person, including any organ of state or community, providing or giving access to the indigenous biological resources to which the application relates; and
(b) an indigenous community or a specific individual-
(i) whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting; or
(ii) whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting.