South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework

Guidelines for Providers, Users and Regulators

environmental affairs

Department:
Environmental Affairs
REPUBLIC OF SOUTH AFRICA

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Guidelines for Providers, Users and Regulators

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Published by:
Department of Environmental Affairs
The Director-General
Private Bag X 447
Pretoria
0001
Call centre: 086 111 2468
www.environment.gov.za

ISBN 978 0 621 40885 0

Acknowledgments
We are grateful for the input provided by participants at regulators, users and providers workshops.

Production
Layout: Page Arts
Photographs: Cover: Harvesting aloe (Ulrich Feiter); Page 1, Baobab (Glyn Williams); Page 9, Pincushion (Johanna von Braun); Page 23, Aloe seedlings (Ulrich Feiter); Page 41, Vygies (Johanna von Braun); Page 57, Illustration of *Sutherlandia fructescens* (cancer bush) (South African National Biodiversity Institute).

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Bomo Edith Edna Molewa

Foreword

Biological resources, similar to other key resources, are not distributed evenly in the world. South Africa is known as a treasure trove of natural resources, boasting an incredible biological diversity of 10% of the world's plants, 7% of the world's reptiles, birds and mammals, 15% of known coastal marine species, and one entire floral kingdom within its borders. Adding to this richness, a diversity of cultures, contained on 2% of the world's land surface, and the use of indigenous biological resources as one of the primary sources for healing of ailments and for symbolic purposes, makes it easy to understand why South Africa is considered to be the third most mega-diverse country after Indonesia and Brazil.

There is a growing global recognition that biological resources are vital to humanity's economic and social development for present and future generations. At the same time, the threat to species and ecosystems has never been as great as it is today. Species extinction caused by human activities continues at an alarming rate.

To address the challenge of biodiversity loss, the Department of Environmental Affairs promulgated and administers the National Environmental Management Biodiversity Act, 2004 (Act No. 10 of 2004) (NEMBA or Biodiversity Act) and the Bioprospecting, Access and Benefit Sharing (BABS) Regulations of 2008, among other legislative tools.

The objectives of the Act are the conservation of biological diversity; sustainable utilisation of indigenous biological resources; and the fair and equitable sharing of benefits among stakeholders, arising from bioprospecting involving indigenous biological resources. Furthermore, the Act seeks to give effect

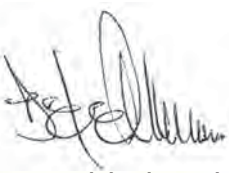
to the ratified international agreements relating to biodiversity which are binding on the Republic, such as the Convention on Biological Diversity (CBD) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Chapter six (6) of the Biodiversity Act regulates bioprospecting involving indigenous biological resources, the export thereof for bioprospecting or any other kind of research, and provides for fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources and their associated traditional knowledge. This chapter further give effect to South Africa's obligations as per the recently adopted Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arsing from their Utilization (in short referred to as "the Nagoya Protocol on ABS").

The Biodiversity Act is further complemented by the Threatened or Protected Species (TOPS) Regulations, CITES Regulations, the National Biodiversity Framework, the Provincial Ordinances, the Patents Amendment Act, 2005 and the Indigenous Knowledge System Policy, as well as various norms and standards for biodiversity management.

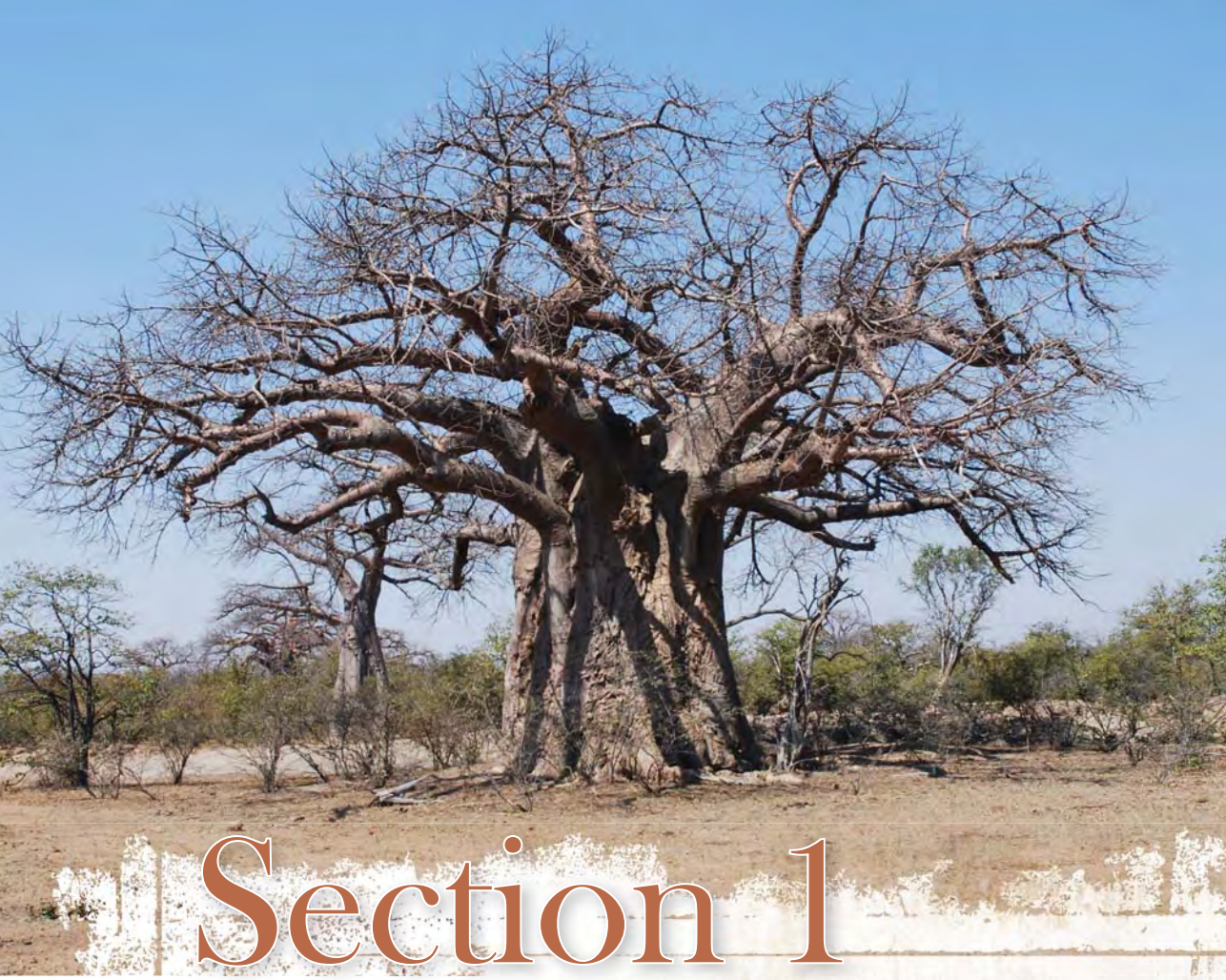
The Department of Environmental Affairs has been actively involved in capacity building and raising awareness of the regulatory requirements since the Biodiversity Act was promulgated. Through this process, it was recognized that tools are required to support stakeholders in ensuring the fair and equitable negotiation and conclusion of Benefit Sharing and Material Transfer Agreements. As such, this set of guidelines was developed to further promote and facilitate practical implementation.

These guidelines are for providers, users and regulators of the use of biological and genetic resources as well as the associated traditional knowledge, and they outline a practical approach for compliance with the legislation. The guidelines endeavour to assist different stakeholders to understand the legal requirements and their rights in terms of the law. It is therefore imperative that these guidelines are consulted when planning to engage in commercial bioprospecting. Doing so will enhance the fair and equitable sharing of benefits arising from bioprospecting projects which utilize indigenous biological resources and their associated traditional knowledge. I would like us to borrow from the wise words of E. O. Wilson, who said that "We should preserve every scrap of biodiversity as priceless while we learn to use it and come to understand what it means to humanity."

I sincerely hope that this set of guidelines will, along with other tools, contribute effectively to the successful implementation of the regulatory framework for Bioprospecting, Access and Benefit Sharing in South Africa, and to meeting our objective of the creation of a better South Africa, a better Africa and a better world.



Bomo Edith Edna Molewa
Minister of Water and Environmental Affairs



Section 1

Introduction

Adansonia digitata **(baobab)**
Source: South African National Biodiversity Institute

Siphonochilus aethiopicus **(wild ginger)**
Source: South African National Biodiversity Institute

1. Introduction

1.1 Bioprospecting, access and benefit sharing

The past two decades have witnessed a shift in approach towards the international trade in biological resources. Concern over the increasing inequality of exchange patterns between user nations (often technologically advanced but biologically poor) and provider nations (often economically poor but biologically rich) and growing recognition by providers of the value of their biological resources, has led to international agreements as well as policies and laws on a national level which aim to redress the inequities of the trade in biological resources. These new legal approaches recognise that those who are involved in harvesting or collecting biological resources to supply the trade are usually the poorest members of society. They also acknowledge that the holders of traditional knowledge (TK) who may have contributed to discoveries should be justly rewarded.

The 1992 Convention on Biological Diversity (CBD) laid down a new way of treating trade in genetic resources and regulating bioprospecting. This has been described as the 'Grand Bargain': in order for users to gain access to genetic resources they must provide fair and equitable benefits to the provider country, including technology transfer, and in order to receive those benefits a provider country must facilitate access to genetic resources. This process is called 'access and benefit sharing', or 'ABS'. Many of these concepts were developed and refined in the Bonn Guidelines, a voluntary agreement which aims

to provide further guidance about ABS implementation. However, many believe that such measures are insufficient to curb the misappropriation of resources and knowledge. Since 2002, parties to the CBD have been negotiating an international ABS Protocol to address these concerns. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was adopted in 2010 at the 10th Conference of the Parties to the CBD and sets in place a legally-binding agreement specific to ABS.

Other relevant international agreements are the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which creates a multilateral system of exchange for key crops and forages, and the Trade-Related Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization, which sets in place a global intellectual property rights system for agriculture, food and healthcare.

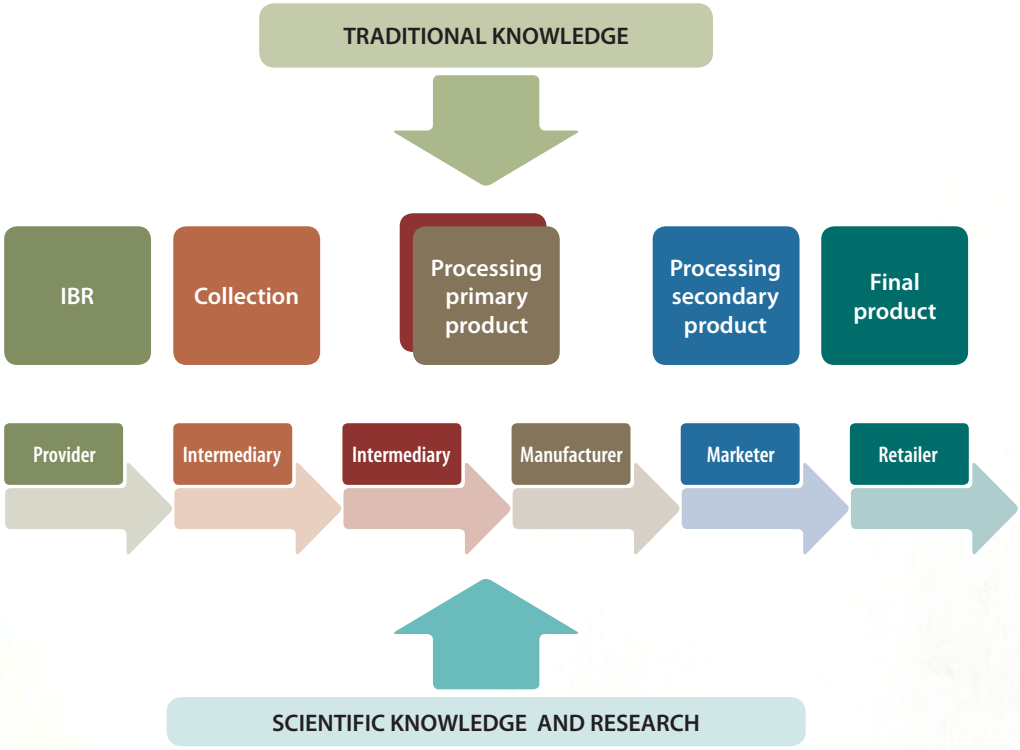
Bioprospecting – the exploration of biodiversity for commercially valuable genetic resources and biochemicals – is regulated in South Africa by the National Environmental Management: Biodiversity Act (NEMBA or 'Biodiversity Act') (Act No. 10 of 2004) and the Bioprospecting, Access and Benefit-Sharing (BABS) Regulations, 2008. The Department of Environmental Affairs (DEA) administers these laws and also acts as the clearing house, or national focal point, for ABS. However, a host of other laws, administered by several other government departments, also have relevance. These are summarised in **APPENDIX 5**. Of particular relevance are amendments to South Africa's Patents Act No. 57 of 1978, which require patent applicants to disclose the origin of genetic material and traditional knowledge and show that they have obtained prior informed consent (PIC) and shared benefits. An important recent initiative is the gazetting of the Intellectual Property Laws Amendment Bill (2010) which provides for copyright, designs and trademarks to be used to provide protection of names or features associated with traditional knowledge.

South African law has a very wide definition of bioprospecting, in contrast to the narrow definition of genetic resources embraced by the CBD. The CBD definition was based on traditional bioprospecting activities such as the screening of biological material for new genes or chemicals to be incorporated into new drugs. However, over the past few decades there has been a surge in the use of natural products in other industries such as cosmetics, herbal preparations and foods, along with an increase in patenting in these sectors. The South African law reflects these trends. The Biodiversity Act thus 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. This definition therefore includes all indigenous species in South Africa as well as the use of their genes or biochemicals. The term 'bioprospecting' is defined to include 'any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation'.

Bioprospecting is about the processing of indigenous biological resources – that is, the 'raw material' up to the point where the resulting product is ready to be sold to consumers, but it does not include the sale itself. What is not always clear is whether the person conducting the research or the person that harvests and trades in the resource should apply for a bioprospecting permit. The approach adopted by DEA is to require the person trading biodiversity to apply for a bioprospecting permit if the **intention** of the trade is to facilitate bioprospecting. If a person multiplies or sells indigenous biological resources for the development and production of products such as medicines, industrial enzymes, essential oils, food flavourants, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts, new plant varieties and so on, it is considered part of bioprospecting and a bioprospecting permit is required. Cultivation of indigenous biological resources or the trade in raw material in its original form, for example rooibos plants, may be bioprospecting, depending on the use of the resource. That is, if rooibos tea is cultivated for the beverage market and sold as a tea, it is not bioprospecting but if the plant is used to make an extract for incorporation into another product this is considered bioprospecting. Whether or not traders must apply for a bioprospecting permit will depend on the ultimate goal of their actions.

FIGURE 1

UTILISATION OF INDIGENOUS BIOLOGICAL RESOURCES FOR BIOPROSPECTING



1.2 Key elements of the Biodiversity Act and BABS Regulations

The Biodiversity Act and BABS Regulations set out important requirements for those using indigenous biological resources.

- Anyone carrying out bioprospecting involving indigenous biological resources and, if applicable, associated traditional use or knowledge, requires a permit.
- Anyone exporting indigenous biological resources for the purposes of bioprospecting or other research requires a permit.

A permit will only be issued if there has been material disclosure to stakeholders, if their prior informed consent to the bioprospecting has been obtained and if the Minister is satisfied that certain conditions, as set out in the legislation, have been met.

The Act includes two categories of stakeholders whose prior informed consent to a bioprospecting project must be obtained. They are:

- those who give access to the indigenous biological resources (e.g. a land owner); and
- indigenous communities whose knowledge or traditional use of indigenous biological resources has contributed to, or may contribute to, the bioprospecting.

Benefit-sharing agreements must be entered into with both categories of stakeholders and, in addition, a material transfer agreement must be entered into with stakeholders who give access to the indigenous biological resources.

The Act also establishes a Bioprospecting Trust Fund, into which all money arising from benefit-sharing agreements must be paid, and from which all payments to stakeholders will be made.

Importantly, the Act and the BABS Regulations make a distinction between the 'discovery phase' of a bioprospecting project and the 'commercialisation phase'. In the discovery phase, researchers attempt to find out if an indigenous biological resource has any potential to be further developed into a commercial product. In the commercialisation phase, commercial potential has already been identified in the indigenous biological resource. Those doing discovery phase research need to notify the Minister about what they are doing, but do not require a bioprospecting permit. A bioprospecting permit is needed only for the commercialisation phase.

The Minister of Water and Environmental Affairs is the issuing authority for bioprospecting permits.

Foreign individuals or companies must apply jointly with South African individuals or companies for bioprospecting or export permits.

Export of indigenous biological resources must be for a purpose that is in the public interest.

A benefit-sharing agreement template is included in the BABS Regulations. This lists possible monetary and non-monetary benefits that may be appropriate (see also APPENDIX 3).

BOX A

PRIOR INFORMED CONSENT

Before access to biological resources or traditional knowledge can commence, the **prior informed consent** from owners of biological resources or traditional knowledge holders is required. The party requesting material or information is expected to disclose fully the intended use of a resource, and the method of collection, in order that the provider of the resource or the knowledge can make an informed decision about whether to provide access.

BOX B

TRADITIONAL KNOWLEDGE AND INDIGENOUS KNOWLEDGE

The terms **traditional knowledge** and **indigenous knowledge** are often used interchangeably but can also mean different things. Traditional knowledge, for example, may imply old knowledge that has been passed on through generations, and is often related to time. Indigenous knowledge may refer to the knowledge of people of a geographical area, who may hold traditional knowledge but also have evolved technologically advanced knowledge. In South Africa both terms are used in different pieces of legislation but their meanings are not consistent. To avoid confusion, these guidelines use traditional knowledge and indigenous knowledge interchangeably to mean the same thing.

BOX C

OPPORTUNITIES FROM SOUTH AFRICA'S BIOLOGICAL WEALTH

After Indonesia and Brazil, South Africa is the third most biologically diverse country in the world, with a high incidence of endemic species. South Africa represents around 2% of the world's landmass, but it plays host to 10% of the world's plants, 7% of all mammals, birds and reptiles, and 15% of all known marine species. Not only does this biodiversity underpin our very existence, but it also presents a variety of opportunities in the form of marine, freshwater and terrestrial animals, plants and micro-organisms that may be used for scientific research or commercial exploitation. South Africa's biological wealth attracts the interest of scientists as well as a wide range of industry sectors – such as the pharmaceutical, biotechnology, horticulture, botanical medicine, food and beverage, seed, crop protection and cosmetic industries. Apart from this large variety of biological resources, South African communities and individuals also have a wealth of traditional knowledge about the use of indigenous biological resources for medicinal, nutritional and personal care purposes. This combined wealth – of biodiversity and associated traditional knowledge – is one of South Africa's greatest assets and needs to be used in a way which not only contributes positively to the lives of the present generation of South Africans, but will continue to provide benefits for future generations.

An illustration of South Africa's biological diversity which consists of all species of plants and animals, their genetic material, and the ecosystems in which they are found *Illustration: Meg Jordi*

BOX D

CONSERVATION AND SUSTAINABLE USE

South Africa has an abundance of indigenous biological resources, but these resources remain susceptible to depletion if they are not well managed and used in a sustainable manner. Since the majority of biological resources are sourced from the wild, a fine balance needs to be maintained between utilising resources for commercial gain, and preserving wild stocks. Some resources are also used locally, for instance in the preparation of traditional medicine or for subsistence purposes, in which case provision should be made for those who rely on the resource before commercial off-take can commence. Wherever possible, conservation measures such as sustainable harvesting techniques should be used in order to relieve pressure on wild stocks. In some cases commercial cultivation may also be possible, but care needs to be taken that this does not negatively impact wild harvesters who may not have the necessary capacity and resources to engage in cultivation.

BOX E

RESOURCES AND ACTIVITIES EXCLUDED FROM THE LEGISLATION

The following resources and activities are excluded from the scope of the legislation:

- Human genetic resources
- Exotic animals, plants or other organisms
- Resources listed in the ITPGRFA
- Research other than bioprospecting if the research is conducted in South Africa and is not for commercial purposes
- The export of *ex-situ* indigenous biological resources if the export is for research other than bioprospecting, provided that the exporter has concluded an export agreement and notified the issuing authority
- The trade of commercial products purchased from a retailer
- The artificial propagation and cultivation of flora species for the cut flower and ornamental plant markets
- Aquaculture and mariculture activities for consumption purposes

1.3 Groups involved in bioprospecting

Bioprospecting involves a wide range of groups. Typically, it includes:

- Researchers, who collect biological material and may be guided by local or traditional knowledge about the location and use of these resources. Most frequently, these researchers are involved in the 'discovery' phase of bioprospecting, meaning they are still exploring the potential of biological resources. Researchers may be local, based at a South African university or research institute, or they may be based outside of the country with South Africa as one of their research sites. Different rules apply for local and foreign researchers and for the different activities they are involved in.
- Those who own or control the land upon which the resource occurs. This may be an individual farmer, a community, a government agency such as the South African Defence Force, or a parastatal such as the South African National Biodiversity Institute.
- Traditional knowledge holders, who have particular knowledge about the resource being investigated. In some cases this knowledge may already be publicly available in books or journals but this does not mean that the original knowledge holders should be excluded.
- Depending on the stage of commercialisation, in some cases harvesters or producers of particular species may also be involved.
- A complex conglomeration of companies, which vary from large foreign multinationals to local, individually owned firms, and which are extraordinarily diverse – from the pharmaceutical and biotechnology industries through to cosmetics, food, nutraceutical and herbal medicine industries. They may be involved in processing, marketing, resale and retail and may store, transport, process, package and sometimes export the product to other destinations.
- Government departments involved in administering particular laws. The DEA, for example, is involved as the issuing authority for bioprospecting permits, while different provincial departments remain responsible for issuing collecting and research export permits.
- Non-governmental organisations (NGOs) may also be indirectly involved as they may represent the interests of communities or provide a wider public voice for issues of concern.

1.4 Purpose of the guidelines

This document forms part of a set of guidelines developed by the DEA to guide implementation of the Biodiversity Act and the BABS Regulations. Nothing in the guidelines should be interpreted to change the existing legal rights and obligations of stakeholders as outlined in NEMBA and the BABS Regulations.

The **intended audiences** for the guidelines are:

- **Providers** of indigenous biological resources and/or traditional knowledge (e.g. indigenous and local communities, traditional healers, *ex-situ* collection holders, organs of State and private, public and communal landowners).
- **Users** of indigenous biological resources and traditional knowledge (e.g. companies, bioprospectors, and researchers who use indigenous biological resources and traditional knowledge).
- National and provincial government departments that are responsible for implementing the BABS Regulations (referred to as **'regulators'**).

The **purposes** of the guidelines are:

- to assist these different groups to understand the legal requirements of Chapter 6 of NEMBA on bioprospecting, ABS and the associated BABS Regulations, and their rights under the law;
- to increase awareness about some of the basic principles and concepts of ABS;
- to provide guidance regarding the negotiation, conclusion and evaluation of material transfer and benefit-sharing agreements; and
- to assist both providers and users in building a mutually beneficial relationship through efficient access to indigenous biological resources and traditional knowledge, and the fair and equitable sharing of benefits arising from bioprospecting.

1.5 Structure of the guidelines

The guidelines are structured as follows.

This introductory section:

- introduces the concept of ABS;
- explains the regulatory and policy framework for bioprospecting, access and benefit sharing in South Africa;
- gives an overview of the process to be followed when applying for a bioprospecting permit;
- describes the different groups involved; and
- sets out the background and purpose to the guidelines.

Those familiar with the context of bioprospecting, access and benefit sharing in South Africa may wish to skip this section and go directly to the Guidelines themselves.

Three guidelines have been produced and form part of this document:

I. Guidelines for **providers** of indigenous biological resources and traditional knowledge.
II. Guidelines for **users** of indigenous biological resources and traditional knowledge.
III. Guidelines for **regulators**.

Section 2

Guidelines for providers of indigenous biological resources and associated traditional knowledge

Packing marula *Source: Myles Mander*

2. Providers

2.1 Introduction

This section is intended for providers of indigenous biological resources and indigenous communities or individuals whose traditional uses or knowledge will be used for bioprospecting. Providers are divided into those who provide access to the indigenous biological material, those who provide the material itself, those who provide information on traditional use or knowledge associated with indigenous biological resources – or combinations of these three.

2.2 Providers of indigenous biological resources and traditional knowledge

Different kinds of providers envisaged by the law

Providers of indigenous biological resources: Providers of indigenous biological resources can include any individual, company, landowner, organ of state or indigenous community that owns or controls the indigenous biological resource. The right to provide access to an indigenous biological resource can be through ownership of the resource itself or ownership or control over the land on which it grows or is found. Thus, examples of providers are local communities, private land owners, public landowners

(e.g. national government departments such as the Department of Transport, municipalities, SANParks, provincial reserves), botanical gardens, holders of *ex-situ* collections (e.g. museums, universities, genebanks, herbaria), or other countries through their National Competent Authority.

Providers of traditional knowledge: In most cases an indigenous community will be the provider of traditional knowledge but the Biodiversity Act also specifies that an individual can be the provider of traditional knowledge.

2.3 The distinction between the discovery phase and the commercialisation phase

It is important to be aware that benefits will be different at the different phases of bioprospecting. The Biodiversity Act distinguishes between the discovery phase and commercialisation phase of bioprospecting. The discovery phase is when scientists are trying to find out if there is any potential in the indigenous biological resource that could be further developed into a commercial product. The commercialisation phase is when something with commercial potential has already been identified in the indigenous biological resource. It is difficult to know what benefits will arise from the discovery phase because the commercial viability is not yet known. However, as a provider, you could decide to provide your traditional knowledge and/or indigenous biological resources on condition that you share in some benefits that would be negotiated.

2.4 Access to indigenous biological resources and knowledge

Reasons for users wanting to have access to the biological resources on your land

Indigenous biological resources are used as important ingredients by many different industries. These ingredients may form part of medicines, cosmetics, foods with health benefits (called functional foods), herbal food supplements, or dyes and other chemicals. In such cases the indigenous biological resources are used for their medicinal or other properties. However, researchers spend a long time isolating these properties and testing them for safety and efficacy before products reach the shelves.

Your land may contain interesting indigenous biological resources for bioprospecting. You have the right to control access to the resources on your land. Nobody can have access to your land without first getting your informed consent. This means that any user who wants to have access to your land and collect any resource that occurs on your land will first have to get your permission and give you information about what they plan to do with the resources and what the expected outcomes are. If you own the land communally then you, along with your community, will have to decide whether you will allow the bioprospector to have access to your land and its resources.

If the resource that is collected is used for bioprospecting, a bioprospector has to share some of the benefits that might be generated. There are a number of ways in which this might happen, for example through fees or community development projects (see **APPENDIX 3** for more information).

Reasons for users wanting to have access to your traditional knowledge

There are a great variety of plants, animals and other organisms in the natural environment, not all with medicinal or other properties. Often it takes a long time to identify the useful resources and their properties. Many indigenous communities have a deep understanding of the value of the plants and animals in their local ecosystems and use these resources for many purposes, including as medicine, and

food. Over generations they have developed unique knowledge of these resources. This knowledge can be of great value for bioprospectors. Not only can it speed up the process of identifying useful plants and resources, but it can also indicate how resources may be used.

Traditional knowledge holders are not required to share their knowledge with outsiders. However, if they do decide to share their knowledge they have a right to know what the knowledge is going to be used for. If the community rather than an individual holds this knowledge, the community must be involved in decisions about knowledge sharing, and the conditions for doing so. Traditional knowledge holders have a right to share in some of the benefits that may result from the use of such knowledge (see APPENDIX 3).

2.5 Communally owned indigenous biological resources or traditional knowledge

There are a few issues to bear in mind when resources and knowledge are collectively owned:

- The person who provides the communally owned indigenous biological resource or traditional knowledge should be an authorised representative of the community who has the consent of the community, and this should be verifiable.
- The community should be fully informed about the intended use of the indigenous biological resource or traditional knowledge by the bioprospector prior to providing their consent.
- The community should collectively share the benefits arising from bioprospecting based on use of their indigenous biological resource or traditional knowledge.
- The community has the right to refuse access to indigenous biological resources or traditional knowledge.

According to the BABS Regulations, consent will be recognised as genuine only if it is through a resolution (see APPENDIX 4) adopted by the indigenous community which confirms that:

- its representative has been authorised to enter into a benefit-sharing agreement on behalf of the community;
- the community has full knowledge of the bioprospecting project ; and
- the community consents to entering into the agreement.

Typically, indigenous communities have traditional or customary systems that they use to make decisions and these may take a number of different forms.

BOX F

PUBLICLY AVAILABLE TRADITIONAL KNOWLEDGE

Traditional knowledge under the Biodiversity Act and BABS Regulations relates to the discovery or use of indigenous biological resources. People who do not belong to the indigenous community that has developed or discovered this knowledge could also be aware of this knowledge through learning of it from books, articles, media or interactions with community members. Traditional knowledge that is not exclusively known by the indigenous community that has developed or discovered it, is commonly referred to as being in the 'public domain'.

However the fact that this traditional knowledge is in the 'public domain' does not imply that the indigenous community which developed or discovered it no longer has any rights over it. On the contrary, any use of this knowledge for bioprospecting would require the consent of the indigenous community which has developed or discovered it.

Sometimes traditional knowledge is also considered to be in the 'public domain' if it is widely shared among a number of indigenous communities and there is no clarity as to which specific community developed or discovered the knowledge. This raises the question as to which community has the right to give consent for the use of the traditional knowledge for bioprospecting. The Biodiversity Act and the BABS Regulations do not exclude the possibility that more than one indigenous community can provide consent to different bioprospectors for use of the same traditional knowledge.

There is also the possibility that different indigenous communities that share traditional knowledge could come together and collectively decide how to provide consent for the use of their traditional knowledge, discuss the terms of such consent, and determine how they will share the benefits arising from use of their knowledge. This has happened between the San and Nama in the cases of *Hoodia* and *Sceletium*.

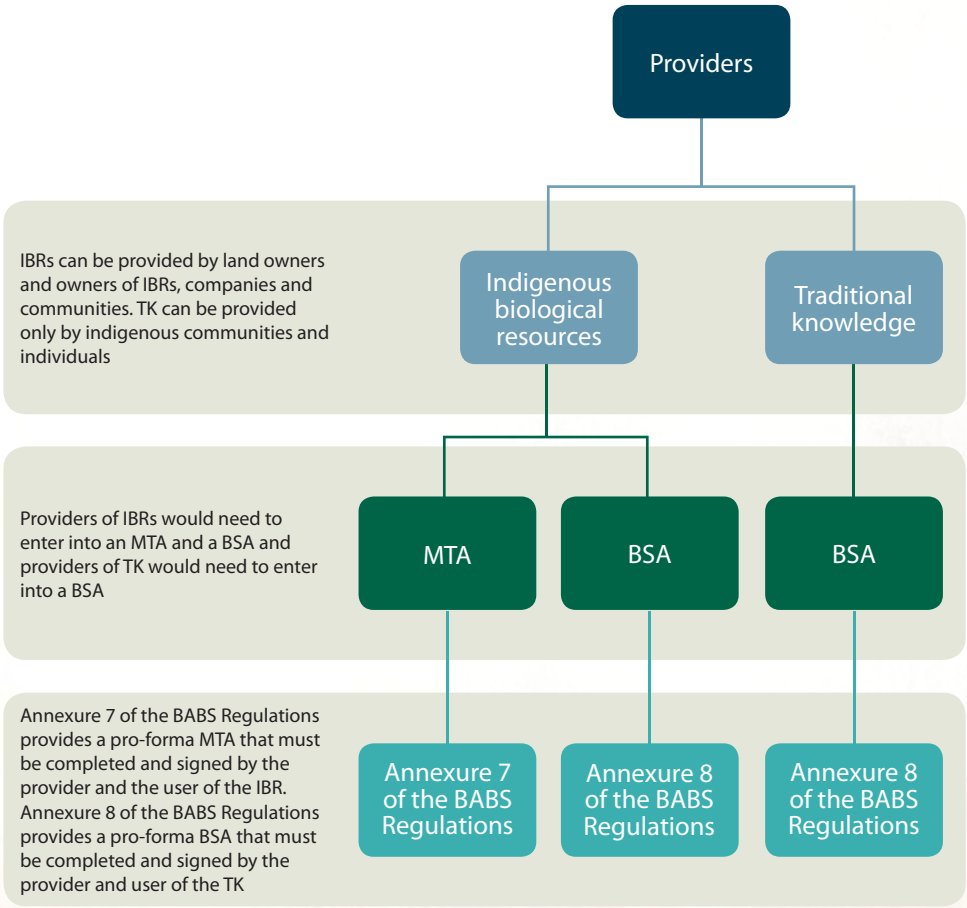
Portulacaria afra (spekboom) *Source: Anthony Mills*

2.6 Starting the access and benefit-sharing process

The flowchart below sets out a step-by-step guide to the ABS process for providers of indigenous biological resources and traditional knowledge. It is important to note that communities providing access to traditional knowledge may not be the only owner of such knowledge. In some cases other indigenous communities may hold the same knowledge and could request to be included in a benefit-sharing agreement.

FIGURE 2

ACCESS AND BENEFIT-SHARING PROCESS FLOWCHART



MTA = material transfer agreement
BSA = benefit-sharing agreement

BOX G

USEFUL QUESTIONS YOU MAY WANT TO ASK A POTENTIAL USER BEFORE GIVING CONSENT

Who are you and which company/institution are you doing the research for? Do you have a business card or official documentation that can prove you are working for this company/institution?

What indigenous biological resources would you like to do your research on? Can you provide us with the scientific name/s of the resource?

What traditional knowledge are you intending to use?

What do you want to use the research for?

If you are an international company/researcher, where will the research take place? Are any local or national institutions participating in the research?

Will there be any other third parties involved in doing research on the resource?

What is the budget for your research?

What types of commercial returns are you expecting? Are there any other kinds of benefits that you are expecting from the resource or traditional knowledge? Are there other benefits from the research or commercialisation? Will you be employing any members of the community in this process?

What benefits will you bring to the community? How do you plan to share these benefits with us?

When are you expecting to receive any benefits from the use of the resource or traditional knowledge?

As of when and for how long will you want to have access to our resources and how much are you intending to collect? Where will you be collecting the resource? Can we be included in the process of collecting or harvesting the resource?

Will the harvesting of the resource have any impact on the ecosystem? Will there be any negative environmental consequences from the harvesting?

How will you ensure the confidentiality of the traditional knowledge we may provide you with?

How will you keep us updated on ongoing progress in your research and development?

Who is a contact person (preferably within South Africa) we could approach should we have any further questions?

When is a material transfer agreement required and when is a benefit-sharing agreement required?

1. A material transfer agreement **and** a benefit-sharing agreement are required when the bioprospector needs access to your indigenous biological resources. In other words, you never have a material transfer agreement without a benefit-sharing agreement.
2. A bioprospector that is provided with traditional knowledge and access to the indigenous biological resource for the purposes of bioprospecting requires both a material transfer agreement **and** a benefit-sharing agreement.

3. If the bioprospector does not need access to the indigenous biological resources (for example, because it is on his or her own property) and is not making use of indigenous knowledge, no agreements are required. **However**, a bioprospecting permit is still required.
4. An indigenous community that consents to use of traditional knowledge for the purposes of bioprospecting **only** needs a benefit-sharing agreement and not a material transfer agreement.

BOX H

A NON-DISCLOSURE AGREEMENT

A non-disclosure agreement is a legal contract also known as a confidentiality or secrecy agreement entered into by at least two parties. This agreement outlines confidential information (such as traditional knowledge) that one party wishes to share with another for a specific purpose, but to which it wishes to restrict access by third parties. Thus, it is a contract through which the parties agree not to disclose information covered by the agreement. The parties can include other conditions in this agreement if they so wish.

2.7 Information needed to negotiate material transfer and benefit-sharing agreements

Material Transfer Agreement

If the bioprospectors want to have access to indigenous biological resources on your land during the commercialisation phase of a project, they will have to submit a bioprospecting permit application to the Issuing Authority, which must be supported by a material transfer agreement. This material transfer agreement must be signed by you as the provider of the indigenous biological resources and by the bioprospector, as the user of the resources (see BABS Regulations Annexure 7). **BOX I** sets out the information which must be provided by the bioprospector for you to consider before entering into a material transfer agreement. In addition to this information, the bioprospector may want to provide the indigenous biological resources to a third person. This could be another research institute or a product developer. You as a provider may set conditions on such transfer to third parties, however, you have to ensure that this is stated in the material transfer agreement, and note that the transfer of material to a third party is subject to written consent from the Minister.

If you decide to provide the bioprospector with access to your indigenous biological resources, you will also have to provide some information that he/she will need for filling out the permit application. You should only provide this information once you have decided that you will allow the bioprospector access to your indigenous biological resources. It would include:

- Your own name, identity number and contact details.
- Who you represent in your capacity as the signatory of the material transfer agreement.
- A resolution from the community about access to the indigenous biological resource.
- The present use of the indigenous biological resources in relation to the intended research of the bioprospector. Please note that this may include passing on some of your traditional knowledge to the bioprospector. The use of such knowledge should be reflected in your benefit-sharing agreement with the bioprospector.

BOX I

INFORMATION REQUIREMENTS FOR MATERIAL TRANSFER AND/OR BENEFIT-SHARING AGREEMENTS

- Name of the institution or research body and registration number
- Contact details of the institution, including a physical address, phone number, fax and email address
- Name of a contact person in the institution, including a certified copy of the person's identification document and their designation in the institution
- If the bioprospector is applying as an individual, his/her name, contact details and identification document
- The contact details of the recipient of the indigenous biological resources if this is someone other than the bioprospector
- Exact information of the type, quantity and source of indigenous biological resources which are subject to the bioprospecting
- The time frame of the anticipated research
- The purpose of export if the indigenous biological resources are to be exported
- Intended use of the indigenous biological resources

Benefit-Sharing Agreement

If you decide you would like to provide your indigenous biological resources and/or associated traditional knowledge to a bioprospector, you will have to come to an agreement which outlines how the benefits arising out of such bioprospecting will be shared with you as the provider. The information needed for the agreement is partially the same as that needed for a material transfer agreement (see BOX I).

If you decide to provide the bioprospector with access to your indigenous biological resources and/or traditional knowledge you will also have to provide some information that he/she will need in order to fill out the permit application. You should only provide this information once you have decided that you will allow the bioprospector access to your indigenous biological resources and/or traditional knowledge.

- Your name and contact details and, if applicable, the designation of the person signing the agreement.
- If you agree to share your indigenous biological resources and enter into a benefit-sharing agreement you will have to complete a material transfer agreement (see above).
- If you agree to share your traditional knowledge and enter into a benefit-sharing agreement with the bioprospector, you have to share your knowledge and traditional use associated with the indigenous biological resource. Be aware that the information included in both agreements will be shared with the bioprospector, the DEA as well as the DEA-appointed advisory committee in charge of analysing bioprospecting permits.
- If you are an indigenous community that either provides access to indigenous biological resources or shares your traditional knowledge with a bioprospector then you will have to provide a description of the community, the name and capacity of the individual who represents the community in the negotiations and the contact details of that representative.
- If you are an indigenous community you must adopt a resolution that confirms that the representative identified in the agreement has the authority to enter into such an agreement on behalf of the community. The resolution must also state that the community is fully aware of the bioprospecting project and that it consents to the benefit-sharing agreement (see APPENDIX 4).

- You will have to decide and agree with the user on the type of benefits you would like to receive as part of the benefit-sharing agreement (see **APPENDIX 3** for some examples).
- You will have to decide jointly with the users how often the benefit-sharing agreement is to be reviewed, with a view to amending the agreement where necessary. One month before the review the user must submit any new material information about the bioprospecting. This will allow you to familiarise yourselves with the material before the review.

It is important to note that entering into a benefit-sharing agreement with one bioprospector does not prevent you from entering into benefit-sharing agreements with others, unless this is specifically stated in the agreement (such an agreement is called an exclusive agreement). If you do not want to have an exclusive agreement with a bioprospector, you should be careful not to include such provisions in the agreement between yourselves and the bioprospector.

BOX J

USEFUL QUESTIONS YOU MAY WANT TO ASK A POTENTIAL USER BEFORE NEGOTIATING A MATERIAL TRANSFER AGREEMENT OR A BENEFIT-SHARING AGREEMENT

Before entering into benefit-sharing negotiations you should try to find out as much as possible from the user about expectations of benefits. The following questions may help:

How much are you investing in the research and what are your expectations?

What is the expected outcome of your research? Which market are you targeting? When are you expecting concrete results?

Will you be applying for any intellectual property rights linked to this project?

How likely is it that you will get commercial returns from the bioprospecting? When are you expecting such returns?

Are you expecting to bring the final product to market or are you more likely to sell the outcome of your research to a third party/ another company?

How will you keep us updated about ongoing developments of the research process? How often will we jointly review the agreement?

2.8 The kinds of benefits that can be expected

The types of benefits that you can expect from a benefit-sharing agreement will vary from case to case. You are free to express any preferences you may have about the benefits you would like to see. Usually the types of benefits can be divided into monetary and non-monetary benefits. **APPENDIX 3** gives an overview of the different options that are available but is not exhaustive and can be added to. In addition to these benefits you may want to ensure that local collaborators, assistants, guides and informants are included as paid participants in the research; that local people are trained as appropriate in relevant scientific, legal and management issues; that you are properly acknowledged in the research process; and that you receive copies of photographs, slides and relevant documents.

It is important that you insist on simplified communication material, translated into local languages, including information about the objectives of the bioprospecting project and its progress.

BOX K

THE ADVANTAGES AND DISADVANTAGES OF DIFFERENT TYPES OF BENEFITS

There are many different types of benefits available for providers to choose from in their negotiations with users. None of them are exclusive so you may choose to negotiate several different types of benefits. In deciding on what type of benefit is most suitable for you, you should bear in mind that different benefits come with different advantages. Some of the options, although having the potential of bringing greater profit in the long term, may be riskier and have long delays in receiving the money. For example, royalties from co-ownership of intellectual property rights may generate large profits in the future but only if the bioprospecting results in a marketable product. Also, turning a patent into a product can take many years, which means that benefits can be severely delayed. Some products, such as herbal medicines, are not as lucrative as others, such as pharmaceutical drugs, but may carry a lower risk. Up-front or milestone payments can be negotiated as part of these options and are more immediate and predictable, but may reduce longer-term profits.

The importance of non-monetary benefits needs to be emphasised. In cases where the provider is a community or a group of people any non-monetary benefit that may be of use to the group as a whole may turn out to be a more appropriate form of sharing benefits than monetary returns. Such benefits could be in-kind contributions, such as local job creation and the support of certain infrastructure projects.

There is no formula that will help you decide on the most suitable benefits and each case will be different. However, before entering into negotiations you should think carefully about the type of benefits that are most appropriate for your situation. You will have to determine who should benefit, when and how. **APPENDIX 3** lists a range of benefit-sharing options and separates them into short-, medium- and long-term benefits.

2.9 Concluding material transfer and benefit-sharing agreements

Material transfer and benefit-sharing agreements are legally binding contracts that are entered into between the bioprospector using indigenous biological resources or traditional knowledge, and the provider of such resources or knowledge. A contract is a legally enforceable agreement between two parties. Every contract should have terms and conditions that both parties agree to and should comply with. Non-compliance with the terms and conditions of the contract amounts to a breach of the contract.

Annexure 7 and Annexure 8 of the BABS Regulations contain standard format material transfer and benefit-sharing agreements. These standard format agreements must be used but additional terms and conditions can be included in the standard form agreement, if necessary in an annexure – for example, conditions dealing with termination of the agreement, confidentiality of information, and what happens if either party to the agreement doesn't keep to the agreement (breach of agreement).

2.9.1 Receiving monetary benefits

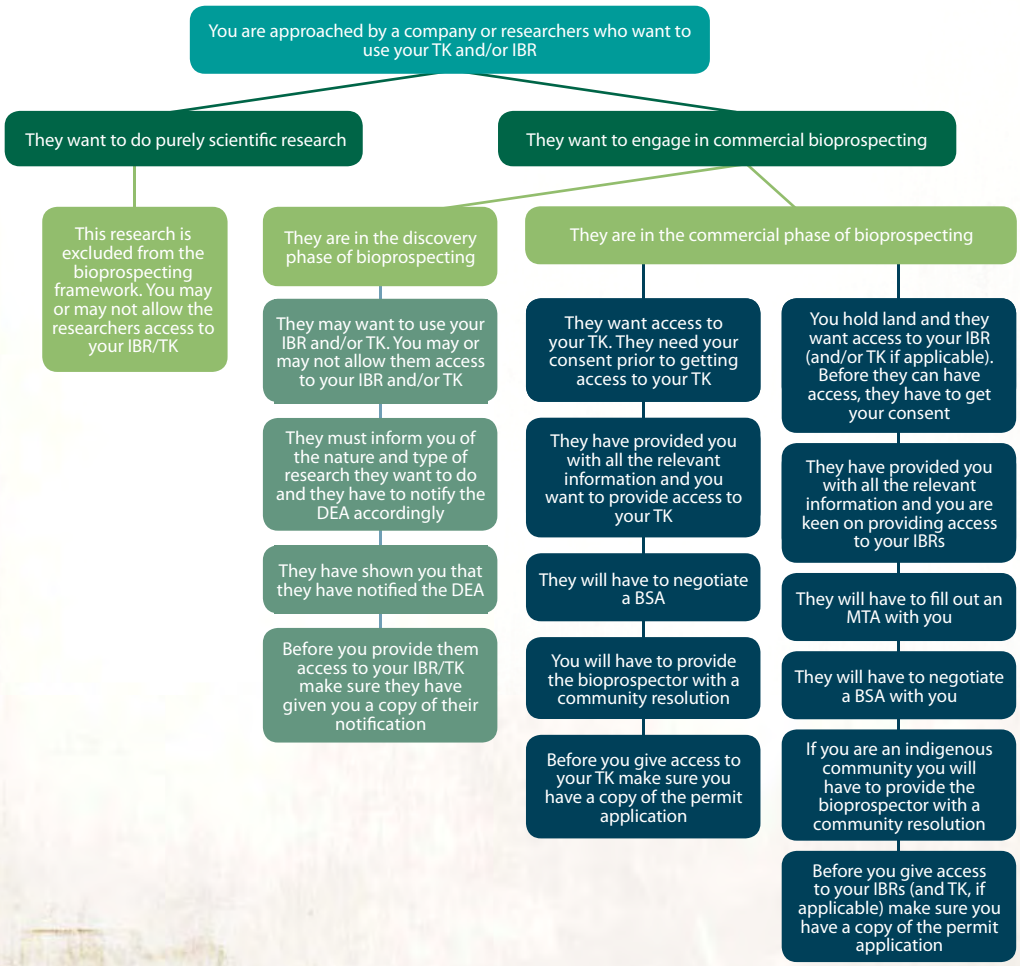
In terms of the Biodiversity Act, the government must establish a Bioprospecting Trust Fund into which all monies arising from benefit-sharing agreements must be paid. The Director-General of the Department is responsible for the administration of this fund. Money received by the fund will be paid out annually to the providers of traditional knowledge and/or indigenous biological resources, unless the benefit-sharing agreement stipulates a different period for paying out monetary benefits. This means that the bioprospector does not pay you directly.

2.9.2 Enforcing agreements

It is important to clearly state in the agreement how disputes relating to the agreement will be resolved. Courts are not the only option available to deal with a breach of an agreement. Agreements can also state that conflicts that arise should be referred to a mediator who will help the parties work through their differences. If the meditation fails then the parties can refer the matter to an arbitrator whose decision will be final. Agreements that provide for mediation and arbitration must also say how the mediator and arbitrator will be appointed and what should happen if the parties to the agreement cannot agree on who to appoint. The agreement should also say who will pay the costs of litigation, mediation or arbitration. Where breach of agreement is experienced, providers can also approach government for assistance (see **BOX M**).

FIGURE 3

BIOPROSPECTING, ACCESS AND BENEFIT-SHARING PROCESS OVERVIEW



BOX L

COMMUNITY PROTOCOLS

The standard format benefit-sharing agreement in Annexure 8 of the BABS Regulations requires a resolution adopted by the indigenous community indicating that it has full knowledge of the bioprospecting project, has consented to entering into the benefit-sharing agreement and has authorised its representative to enter into the agreement on the community's behalf.

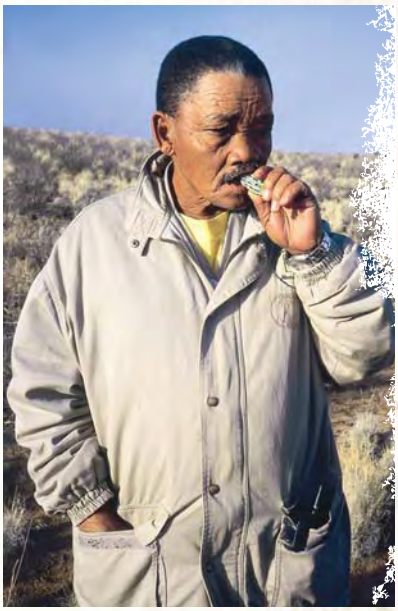
While a resolution is specifically related to the bioprospecting project at hand, some indigenous communities, like the Bushbuckridge Traditional Health Practitioners, have begun to develop 'community protocols' which act as charters developed by the indigenous community outlining their values, customary laws and norms, relationship to traditional knowledge and leadership structures. A 'community protocol' is therefore an interface document developed by an indigenous community that is a result of extensive consultations within the community and is designed to clearly present to the government and potential bioprospectors the process of engaging the community and how the community makes decisions. A 'community protocol' ultimately seeks to provide predictability, clarity and transparency about community values and decision-making processes.

A community protocol helps to ensure that any community resolution as required under Annexure 8 of the BABS Regulations is not an ad-hoc decision but is based on good community process. It therefore provides the government with a clear way of verifying the integrity of the community resolution and provides potential bioprospectors with clear steps to follow when engaging with the indigenous community. A community protocol is not required by the legislation but is a tool that communities can consider using.

2.10 Support for negotiating material transfer and benefit-sharing agreements

Ensuring that negotiations to develop material transfer and benefit-sharing agreements are on an equal footing

The Biodiversity Act and the BABS Regulations provide that government must ensure that agreements between providers and users of indigenous biological resources and associated traditional knowledge are fair and equitable. In some cases, government may intervene to facilitate the negotiations around an agreement and provide support to providers of indigenous biological resources and associated traditional knowledge. Providers can ask government for this support (see BOX M).



The late Vetman Piet, demonstrating use of *Hoodia*
Source: Rachel Wynberg

BOX M

HOW CAN THE DEPARTMENT OF ENVIRONMENTAL AFFAIRS HELP?

The DEA can assist providers of indigenous biological resources and traditional knowledge with:

- facilitating the negotiations between the permit applicant, i.e. the bioprospector and you, as the provider;
- facilitating verification of user claims about the usefulness of the traditional knowledge and/or indigenous biological resources obtained; and
- acting as mediator to resolve disputes between parties to the agreement.

The DEA is obliged to:

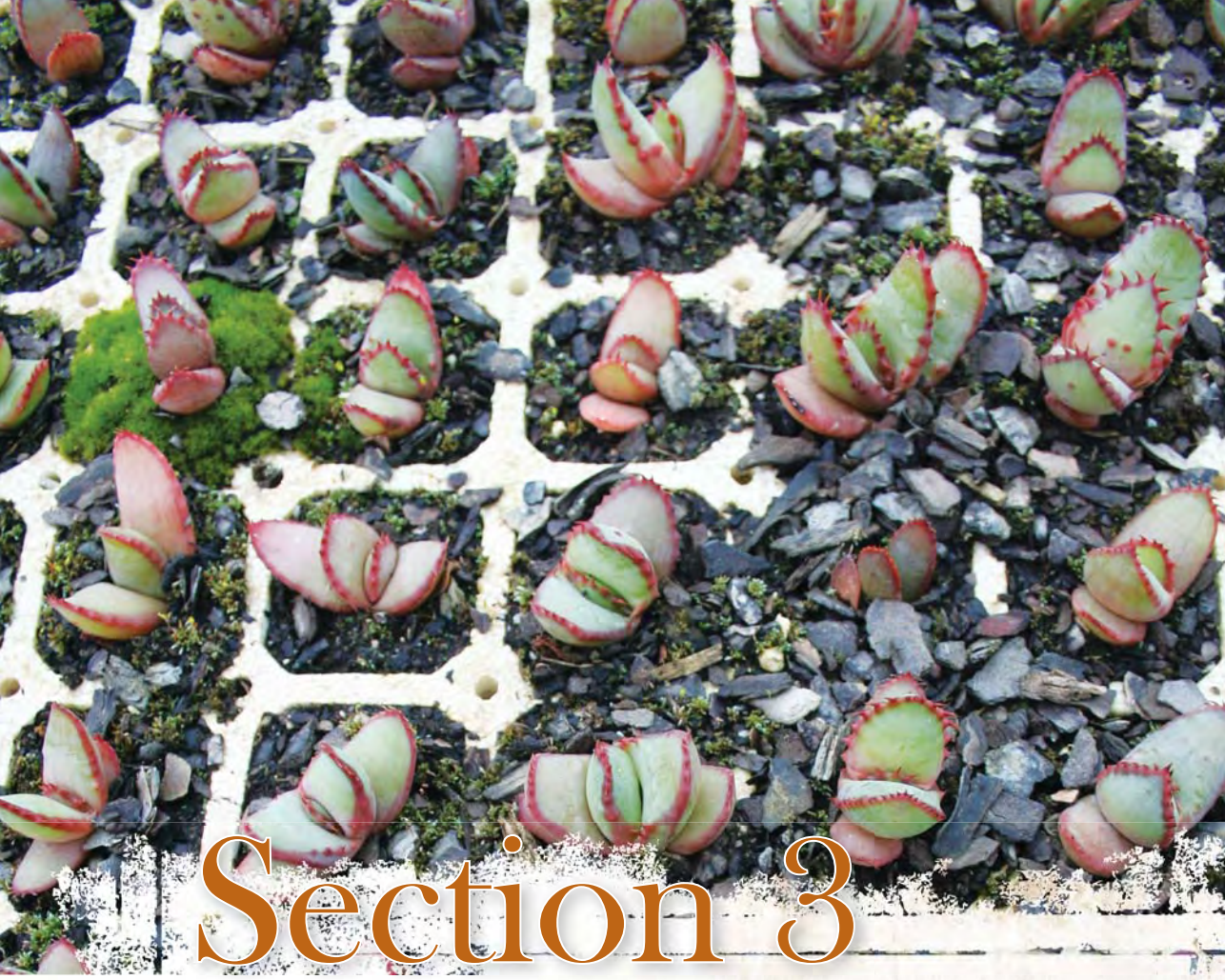
- monitor compliance by the permit holder, i.e. the bioprospector who obtained a permit, with the conditions of benefit-sharing agreements and material transfer agreements entered into;
- assist in obtaining Ministerial approval of the concluded benefit-sharing agreement between parties to make it a legal document;
- enforce the law to ensure that bioprospectors adhere to the conditions of the benefit-sharing agreement and/or material transfer agreement; and
- take legal action against bioprospectors who illegally collect indigenous biological resources.

2.11 Follow-up on agreements

The benefit-sharing agreement in Annexure 8 of the BABS Regulations allows for the agreement to be reviewed. Parties to the benefit-sharing agreement will need to agree on when and how frequently this should take place.

The benefit-sharing agreement should specify intervals at which the bioprospector will report to you as the provider of the indigenous biological resource or traditional knowledge on the status of the bioprospecting project and related benefits. It may be useful to include in the contract the manner, place and medium through which the bioprospector will provide status updates. You could ask for a translation and simple explanation of the reports if this is necessary. A month before the agreement is reviewed the bioprospector should provide any new material information to you to enable you to review the agreement on an informed basis.

You may also wish to nominate an independent expert who would be able to review the status updates and advise you on implications.



Section 3

Guidelines for users of indigenous biological resources and associated traditional knowledge

Hoodia gordonii **in the wild** *Source: Rachel Wynberg*

3. Users

3.1 Introduction

These guidelines are intended for users of indigenous biological resources and traditional knowledge associated with these resources. This may include researchers involved in exploring indigenous biological resources or traditional knowledge for commercial potential; those doing research with no commercial application; companies that are trading or processing indigenous biological resources; or research institutions with active bioprospecting programmes. **BOX N** gives a summary of the different types of users of indigenous biological resources and traditional knowledge. The BABS Regulations will apply differently to these users – or in some cases not at all – depending on the types of activities undertaken.

Drying ***Harpagophytum procumbens*** *Source: Ulrich Feiter*

BOX N

DIFFERENT TYPES OF USERS OF INDIGENOUS BIOLOGICAL RESOURCES AND TRADITIONAL KNOWLEDGE

- Researchers at recognised national tertiary institutions or research institutes
- Exporters/traders of indigenous biological resources
- Multi-national corporations
- Local/foreign processors and manufacturers
- Importers
- Foreign researchers

3.2 Users' activities and corresponding permits

Certain biological resources and activities are excluded from the legislative framework for bioprospecting, access and benefit sharing in South Africa (see **BOX E** on page 7). Therefore, if you are involved in any of the activities listed or use any of the resources mentioned in **BOX E**, these Guidelines do **NOT** apply to you. However, this may change if the nature of your research changes. The following section provides a guide to the permits that are required for different research and commercial activities.

Basic research with no commercial intent

I am a researcher wanting to collect indigenous biological resources for pure scientific research with no commercial intent.

For non-commercial research a collection and/or research permit from the relevant provincial authority may be needed. However, you do not need to apply to the national authority for a bioprospecting permit.

If you want to export material you will need a permit from the relevant provincial authority if the material you intend to export does not come from an *ex-situ* collection such as a museum, herbarium, genebank or registered culture collection.

If the intent of your research changes, you will need to obtain a different permit.

Research other than bioprospecting does not require a permit
Source: DEA

BOX O

ACCESS AND BENEFIT SHARING IN PRACTICE – RESEARCH ON THE VERVET MONKEY

Collaboration is currently underway between one South African and two American universities to study the genetic polymorphism of the vervet monkey (*Chlorocebus aethiops*). The research aims to map the genome and establish the species as a non-human primate model for research. This aspect of the project is pure academic research but the funding agreement of the international research institute requires that the genetic material of the research subject be made available to other researchers. Part of the research also focuses on simian immunodeficiency virus (SIV) of which the vervet monkey is a natural host. From 40–60% of all vervet monkeys are infected with SIV, but do not develop AIDS as humans do from HIV. If the modality for this phenomenon could be described, a treatment for HIV/AIDS may be found. A bioprospecting permit was issued to regulate the export of the genetic material of the vervet monkey and to retain South African control over the genetic material when made available to other research institutes (third parties).

The researchers have concluded benefit-sharing agreements with the provincial authorities, with benefits including information about the species distribution and genetic profile. The intention is that this information will contribute to the protection of the genetic integrity of the species. Other benefits include research collaboration through post-graduate and industry involvement, sharing of intellectual property rights arising from the research and acknowledgement of the access providers in research results.

Tapping *Aloe ferox* sap *Source: Ulrich Feiter*

DISCOVERY RESEARCH TO INVESTIGATE COMMERCIAL POTENTIAL

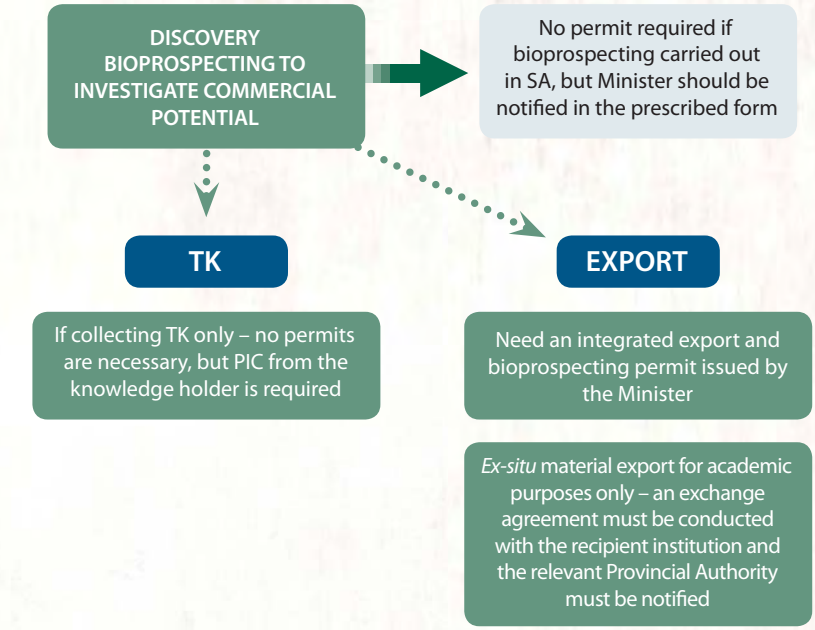
I am a researcher wanting to collect various indigenous biological resources for screening/ discovery or to do further research on their commercial potential.

No permit is necessary in the discovery phase, but a notification procedure has to be followed. You need to notify the Minister of Water and Environmental Affairs of your intent to conduct research on indigenous biological resources for commercial purposes.

If you want to export material you will need to get an integrated export and bioprospecting permit from the Minister.

FIGURE 4

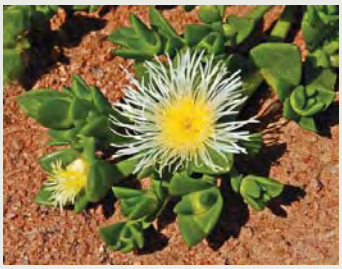
DISCOVERY BIOPROSPECTING AND EXPORT OF INDIGENOUS BIOLOGICAL RESOURCES



Crystallizing *Aloe ferox* sap *Source: Ulrich Feiter*

BOX P

ACCESS AND BENEFIT SHARING IN PRACTICE – COMMERCIALISING *SCELETIUM TORTUOSUM* (KANNA)



Sceletium tortuosum

Washing harvested plants

Sceletium powder ready for distribution

Sceletium tortuosum, popularly known as kanna or kougoed, is a small genus of low growing succulent shrubs endemic to the Western, Eastern and Northern Cape of South Africa. San and Khoi people have long used the plant for its mood-enhancing properties, with records of use dating back as far as 1662. In the 1990s, research was done on kanna in the Paulshoek and Nourivier communities of Namaqualand. The people of these communities are of Nama origin and provided knowledge of the plant to the researcher. The San, however, are considered primary knowledge holders of this use.

A benefit-sharing agreement was negotiated between a local company and the South African San Council (representing the San in South Africa), who elected to include the communities of Paulshoek and Nourivier. The agreement provides for the payment of a fixed monetary value for three years and a percentage of the net proceeds thereafter. It also includes a once-off payment for the development of a product endorsement logo by the San Council and a 1% payment for the exclusive use of the logo. The San Council may use the logo to endorse any other product that is not in competition. This project was awarded the first integrated export and bioprospecting permit by the DEA in October 2010. The product will be developed and initially marketed in the United States of America.

Photo source: HGH Pharmaceuticals

COMMERCIAL PHASE OF BIOPROSPECTING

I am doing research on and/or have developed or identified particular indigenous biological resources for commercial or industrial exploitation. I may wish to file an intellectual property application or begin clinical trials or cultivate a particular resource. I may wish to trade indigenous biological resources for the development of novel products.

You will need a bioprospecting permit from the DEA. The application form for this permit can be found in Part 1 of Annexure 2 of the BABS Regulations.

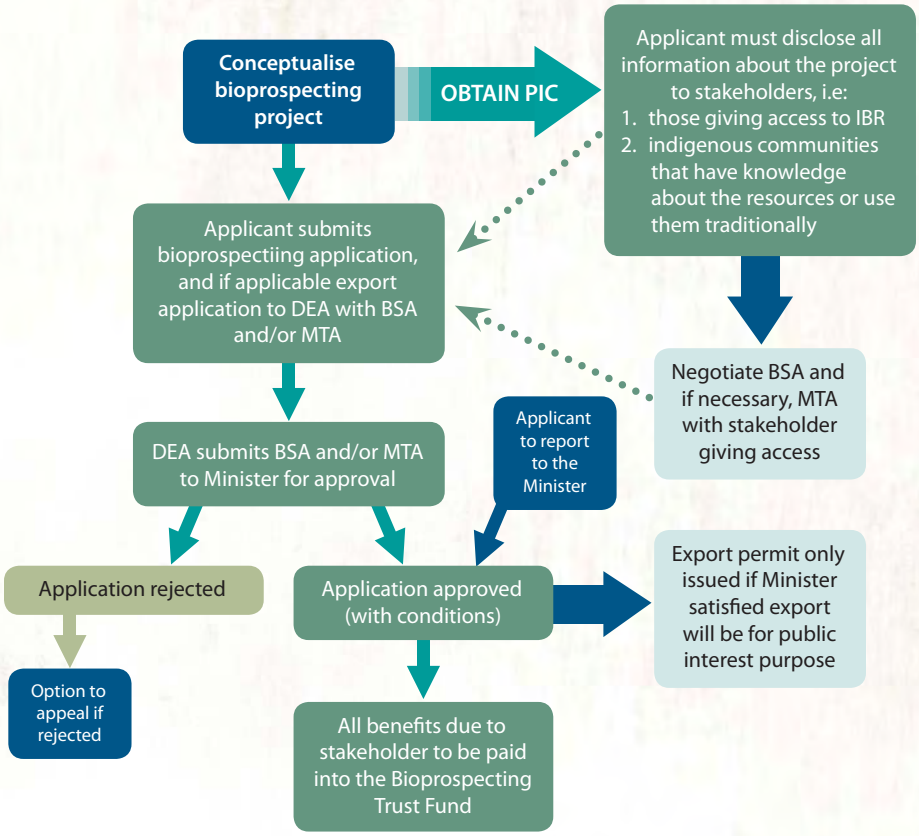
A bioprospecting permit will only be granted if the Minister has approved the relevant material transfer (BABS Regulations Annexure 7) and benefit-sharing agreements (BABS Regulations Annexure 8).

A collection or harvesting permit may also be required from the relevant provincial authority.

If you want to export material you will need to get an integrated export and bioprospecting permit.

FIGURE 5

GENERAL APPLICATION PROCESS FOR COMMERCIAL BIOPROSPECTING



MTA = material transfer agreement
BSA = benefit-sharing agreement

EXPORTING INDIGENOUS BIOLOGICAL RESOURCES

I wish to export indigenous biological resources.

A permit is necessary for export of indigenous biological resources from South Africa, in either the discovery or commercialisation phases of bioprospecting.

If the export is for discovery phase research or commercialisation, an integrated export and bioprospecting permit issued by the Minister is required. The application form for this permit can be found in Part 2 of Annexure 2 of the BABS Regulations.

If the export is for research other than bioprospecting, an export permit issued by the MEC of the relevant province is required. The application form for this permit can be found in Annexure 3 of the BABS Regulations.

3.3 Frequently asked questions about permits

- What are the costs involved in applying for bioprospecting and export permits?

  Annexure 1 of the BABS Regulations sets out the prescribed fees, which are non-refundable. In 2012 a bioprospecting permit cost R5 000; an integrated export and bioprospecting permit cost R5 200; and an export permit for research other than bioprospecting cost R100. Bank account details are included in forms on the DEA website or can be requested from DEA.

- Do I need to apply and pay for both a bioprospecting and integrated export and bioprospecting permit to export indigenous biological resources?

  No. A bioprospecting permit is required for bioprospecting in South Africa. If you intend to export the indigenous biological resources, an integrated export and bioprospecting permit is required. You will be required to pay an application fee depending on which permit you apply for.

- When should I send in my permit application payment to the DEA?

  It is best to send in the permit application first and obtain a reference number for the permit application before the payment is made. Once payment has been done, proof of payment should be sent to the DEA as the permit application cannot be processed if the required non-refundable application fee has not been paid.

- I want to investigate more than one indigenous biological species – do I have to get a different permit for each species?

  No, you may apply for more than one species on the same form.

- We are a group of South African and international stakeholders collaborating – do we each need a permit or can we apply jointly?

  It is possible to have a joint application. During notification in the discovery phase, all the collaborators should be listed, after that one party can assume the position of project leader.

  An international party can apply, but such an application has to be in conjunction with a South African partner.

- I export a resource abroad – do I need to disclose what the buyer intends to do with it?

  Yes. If the resource is going to be used for the development of new products it is considered to be bioprospecting and an integrated export and bioprospecting permit is needed.

- My company only bottles the material but is not involved at any other point along the supply chain. Do I need to apply for a permit?

  If your company simply does the bottling you do not need a bioprospecting permit.

- My company cultivates indigenous biological resources. Do I need to follow the BABS process?

  Yes, a bioprospecting permit is still required, though material transfer and benefit-sharing agreements would not be submitted in support of the permit application. It should be noted that the Minister may issue a permit with additional requirements. You will still be required to conclude a material transfer agreement and benefit-sharing agreement with any subsequent user/buyer of the indigenous biological materials. The benefit accruing to you should, as a minimum, be upfront payment for the raw material.

- I want to export only a sample of an indigenous biological resource. What permit do I need?

  If you are exporting a sample from your ex-situ collection, you simply have to declare to the Provincial Authority that you have exported it and provide a copy of the exchange agreement concluded with the receiving institution.

- My company manufactures a beverage from an indigenous biological resource. Do we need to apply for a bioprospecting permit?

  Trade in raw material in its original form (e.g. rooibos) is not considered bioprospecting, but if the resource is used to make an extract for incorporation into another product it is considered to be bioprospecting. For example, a bioprospecting permit is needed if the indigenous biological resource is used as a flavourant in the beverage (e.g. liqueur flavoured with marula extract) or a carbonated drink, fruit juice, cereal, or porridge flavoured with rooibos tea extract.

FIGURE 6

PERMITS ALONG THE VALUE CHAIN

RETAILER – sells final product in retail outlets	**Permitting arrangements:** No permit required.
INTERNATIONAL BUYER/IMPORTER – extraction, packaging, marketing	**Permitting arrangements:** Permit required. Material transfer agreements with exporter, benefit sharing agreement with harvesters and/or knowledge holders.
EXPORTER – sends material abroad in bulk	**Permitting arrangements:** Permit required. Material transfer agreements with processor and international buyer.
PROCESSOR/INTERMEDIARY BUYER – extraction/basic processing/ packaging/marketing	**Permitting arrangements:** Permit required. Material transfer agreements with exporters or other further users.
HARVESTERS – collect material	**Permitting arrangements:** Provincial harvesting permit required.

3.4 Resource types and collection procedures

Different resources are regulated by different laws and procedures. Use this table as a checklist to determine what procedures and laws apply to the resources you wish to collect.

TABLE 1

KEY TO THE RESOURCE-COLLECTION PROCEDURE

RESOURCE	REQUIRED PROCEDURE FOR COLLECTION	RELEVANT LAW
Non-indigenous biological resources	No bioprospecting permit required. Phytosanitary requirements will apply for export. Phytosanitary permits should be obtained from the Department of Agriculture, Forestry and Fisheries (DAFF).	International standards for phytosanitary measures
Marine biological resources	The Marine Living Resources Act (MLRA) regulates the collection of marine biological resources. As a first step, permission from the Oceans and Coasts (OC) branch of DEA should be obtained before collection.	MLRA, NEMBA, BABS Regulations
Protected species	Check status of species in the Threatened or Protected Species Regulations (TOPS) and comply with these requirements.	NEMBA, TOPS, provincial legislation
CITES-listed species	Besides following the steps for exporting indigenous biological resources, exporters of a CITES-listed species need to apply for a CITES Certificate which is issued by the provincial department responsible for conservation, or the national department – depending on where the resource is found.	NEMBA, NEMBA: CITES Regulation R173
Agricultural genetic resources not listed in ITPGRFA	Indigenous agricultural resources will require permits under NEMBA and the BABS Regulations.	NEMBA, BABS Regulations
Ex-situ IBR in South Africa e.g. gene banks, culture collections, botanical gardens, herbaria and museums	Submit export and research agreement to provincial authority for noting.	NEMBA, BABS Regulations

BOX Q

ACCESS AND BENEFIT SHARING IN PRACTICE – VERIFYING STAKEHOLDERS FOR THE COMMERCIAL USE OF *PELARGONIUM SIDOIDES*

Pelargonium sidoides is a plant species extensively used in South Africa and Europe for respiratory infections, colds and flu ('Umckaloabo' in Germany). The plant has various traditional uses not specifically related to chest infections. A bioprospecting permit application was received by DEA from an international company in collaboration with a South African pharmaceutical company for the exploitation of *P. sidoides*. The permit applicants negotiated benefit-sharing agreements with the royal authority of the Xhosa nation as well as the local communities that provide access to the resource through harvesting on their tribal lands.

The ownership of the traditional knowledge of the use of *P. sidoides* has been controversial as there is a difference of opinion between communities about the ownership of knowledge. DEA in collaboration with the Eastern Cape Department of Economic Development and Environmental Affairs is facilitating a settlement of this question.

A key issue is the lack of data about the population of wild *P. sidoides* and regeneration of the species. To ensure that the species is not depleted beyond a level where its integrity will be jeopardised, a resource and risk assessment is required by law. The management of the resource and the risks to the species are addressed in a Biodiversity Management Plan (BMP). The development of the BMP for *P. sidoides* is led jointly by SANBI and an NGO, TRAFFIC. The BMP was completed in mid-2011 and published for comment .[1]

***Pelargonium sidoides* roots** *Source: Ulrich Feiter*

3.5 Working with traditional knowledge

Any researcher working with traditional knowledge issues, or with the holders of traditional knowledge, needs to ensure that their work is ethically conducted. Researchers need to be aware of the concerns often held by knowledge holders about the collection and use of their knowledge and should approach traditional knowledge holders in a sensitive and culturally appropriate manner. This applies whether you are doing basic research that has no commercial intent or whether you have identified a commercial application. Information about traditional knowledge that is already in the public domain does not mean that the community which developed or discovered this knowledge no longer has any rights over it. Consent is still needed from knowledge holders.

1 *Government Gazette* No. 34487 (29 July 2011).

Any researcher will need to obtain permission from the traditional knowledge holder and get their prior informed consent (see section 3.7). Some research institutions will require you to first obtain ethical clearance. If you plan to publish your work you need to think carefully about the implications, especially if you plan to reveal any knowledge that has been given to you by traditional knowledge holders. If you plan to patent aspects of your work based on traditional knowledge it is vital that you first get prior informed consent and have an agreement in place to benefit knowledge holders. The International Society of Ethnobiology has a useful code of ethics for those working with traditional knowledge holders.

I am a researcher who wants to find out about traditional knowledge associated with indigenous biological resources for pure research with no commercial intent.
No permits are required but you will need to obtain permission from the traditional knowledge holder and get their prior informed consent. You are required to notify the Minister of your research.

I am a researcher who wants to find out about traditional knowledge associated with indigenous biological resources for potential commercial application.
No permits are required but you will need to obtain permission from the knowledge holder and get their prior informed consent, as well as notifying the Minister. Although a formal benefit-sharing agreement is not required for the discovery phase of bioprospecting, even at this early stage it is good practice to ensure that the research will benefit the community or knowledge holder in tangible ways. These need not be monetary. **APPENDIX 3** lists some options you can consider.

I have used traditional knowledge as the primary lead for a new commercial application.
If consent is given you will need to negotiate a formal benefit-sharing agreement. Section 3.6 below describes how you can go about identifying traditional knowledge holders if this is not clear and section 3.8 provides further guidance on negotiating and concluding a benefit-sharing agreement.

3.6 Identifying traditional knowledge holders

If you wish to use traditional knowledge associated with an indigenous biological resource, you need to prove to the DEA that you have done adequate research to identify the potential owners of this knowledge. In addition to fieldwork, this might include a search on the Internet as well as a review of published or archival material.

If you plan an activity which is based on traditional knowledge, but have not identified all the original knowledge holders, you may publish a notice in the media, asking any person or group with traditional knowledge about the resource to come forward. The notice should provide information about the species and properties you intend to investigate, but need not disclose all the details of your intended research. You may also want to contact the local municipality to ask if they can direct you to relevant informants/ knowledge holders to whom you can speak. Local NGOs may also be able to assist in the identification of traditional knowledge holders.

In some cases it may be very difficult to identify the community that provided or holds the knowledge. When a community is identified it may be difficult to verify the legitimacy of these knowledge holders. Also, often more than one community may hold traditional knowledge about the resource. For example, several communities may share a culture but live in many different regions. If you are unable to locate legitimate knowledge holders, or if the knowledge is held very widely by many communities and it is difficult to identify the group you should negotiate with, you should approach DEA for assistance and advice. DEA are well aware of the complexities faced and will take this into account when considering your bioprospecting permit application.

Once traditional knowledge holders are identified you need to:

- get their **prior informed consent** to participate in the research; and
- if bioprospecting is in the commercial phase, negotiate and conclude a **benefit-sharing agreement**.

3.7 Obtaining prior informed consent

- **What is prior informed consent and what information must you disclose?**

  Before access to biological resources or traditional knowledge can commence, the prior informed consent from owners of biodiversity or traditional knowledge is required. This means that you must fully disclose the intended use of a resource, the method of collection, and the intended outcome of the research. You should do this in a manner that is understandable and clear to the traditional knowledge holder, using local languages or translators where necessary. You must do this before obtaining any knowledge. Traditional knowledge holders have a right to refuse access to their knowledge and/or to set conditions for its use.

- **Taking it slowly and building trust**

  Obtaining consent is not a quick, once-off process but is iterative and progressive. It is about building up a relationship of trust, often over years. Although the principle of prior informed consent is not negotiable, circumstances will differ from case to case. All parties need to approach the complex and challenging consent process with a willingness to adapt to circumstances and focus on building relationships over time.

  "An encounter [with indigenous peoples] is more likely to have a good outcome if mutual benefits are on the agenda, agreement is reached about the terms, and … a commitment to a long-term relationship is made."

  [Mason Durie, deputy vice-chancellor at Massey University, New Zealand, and an indigenous Maori].

- **What is the government's role in the prior informed consent procedure?**

  The Minister will need to be satisfied that you have obtained prior informed consent before granting the permit.

- **What evidence can you use to prove you have disclosed information to stakeholders?**

  You can include in your application any letters you may have written to the community, minutes or recordings from meetings, or pamphlets that you may have prepared to explain what you are doing and why. You should ensure that any communication with traditional knowledge holders is in a form that is easy to understand and in an appropriate language.

- **What must you ask providers for and how should evidence of prior informed consent be demonstrated?**

  Proof of prior informed consent from an indigenous community may be provided in the form of a letter or resolution. An example of a resolution is included in **APPENDIX 4**. Providers should be asked to state the name and capacity of their representative; give a description of the community and supply the full contact details of their representative.

- **Who do you approach for prior informed consent?**

  If the resource is held by a private landowner, his or her consent is required. In the event of the State being the landowner, the permission of the relevant department should be sought. If access

to the resource or traditional knowledge (or both) is sought from an indigenous community, then prior informed consent rests with their elected representative. It may not always be clear who this representative is, or there may be several structures representing a community in different forms. Rather than rushing into prior informed consent with an inappropriate institution, it is always advisable to do thorough research first. You may need to seek external help from independent advisors to assist with this process. Although this may be time consuming in the beginning, it will pay off in the long term and will help to prevent problems in the future.

- **How can you ensure that the prior informed consent procedure is valid?**

  Prior informed consent is part of a process of building trust and developing relationships. It does not happen overnight. Communities in South Africa are also very complex and there may be many different types of leadership involved, involving both customary and statutory systems of governance. You may want to work with a local NGO or community organisation to ensure that you are consulting the right people in the community. You can also contact the local municipality for advice.

Prior informed consent and mutually agreed terms are required prior to bioprospecting *Source: Johanna von Braun*

3.8 Negotiating and concluding material transfer and a benefit-sharing agreements

If consent is given to provide access to indigenous biological resources, you will need to enter into a material transfer agreement and a benefit-sharing agreement. If consent is given to utilise traditional knowledge as the basis for the proposed bioprospecting project, you will need to negotiate a benefit-sharing agreement with the group/s or individual/s holding the knowledge. The Minister has to be satisfied that the benefit-sharing agreement is fair and equitable before the bioprospecting permit is granted. If you are uncertain about how to go about negotiating material transfer agreements and benefit-sharing agreements, the DEA is available to assist.

- **What is the difference between a material transfer agreement and a benefit-sharing agreement?**

  A material transfer agreement is an agreement between the permit applicant and the stakeholder providing access to the indigenous biological resource. A benefit-sharing agreement is concluded between the same parties as in the material transfer agreement, but it provides for sharing of benefits which may arise from the bioprospecting project. Whereas a benefit-sharing agreement may sometimes stand alone (for instance when only access to traditional knowledge and not access to the resource is needed), a material transfer agreement is never issued alone, and is always accompanied by a benefit-sharing agreement.

- **What are the basic elements that should be included?**

  Negotiations should take place between legitimate parties. A benefit-sharing agreement should be accompanied by a resolution that confirms the authority of the community representative and indicates that the community has full knowledge of the bioprospecting project and consents to entering into the project. In order to protect all parties to the benefit-sharing agreement, terms and conditions may be included in the standard forms provided in the BABS Regulations. These may include conditions upon which the agreement will be terminated, confidentiality of information provided and liability for breach of the agreement. It is also important to state who will be responsible for costs in the event of a breach of contract being settled in court or through arbitration. You should agree on regular intervals for providing feedback to providers. It is important that this information is contained in simple, non-technical language so that providers can understand the terms and conditions.

- **What are the characteristics of a fair and equitable benefit-sharing agreement?**

  There is unfortunately no formula for a fair and equitable benefit-sharing agreement! Fairness, however, is generally understood to be procedurally fair, and equitable refers to the outcome. Agreements which have been developed through comprehensive consultation and transparent negotiations between stakeholders and with full disclosure of information are more likely to be viewed as fair and equitable.

- **What happens if I need to change the benefit-sharing agreement? For example, my profit may be more or less than originally estimated or the volume of material I collect may be different than that stipulated on the permit?**

  In instances like these, you have to write to the Minister and ask for the existing benefit-sharing agreement to be amended. Other changes to the permit will depend on the nature of the permit, the issuing authority and the permit conditions. In some cases the Minister may approve an amendment to the benefit-sharing agreement which would not affect the validity of the permit.

- **What support can you expect from government?**

  If you can show that stakeholders have been identified but negotiations are not on an equal footing, the DEA can help to facilitate the negotiation process. The DEA may also publish non-confidential parts of the benefit-sharing agreement for public comment to assist with their decision-making.

- **How long will it take to process the permit?**

  The duration of the process depends on the information submitted with the permit application. A permit could be issued in four months if all the permit application requirements are met, sufficient information is provided for the issuing authority to make a decision and there are no queries from the issuing authority.

- **What happens with the permit application after it is submitted to DEA?**

  1. All permit applications are given a reference number once they are received. A formal letter of acknowledgement is then issued to inform applicants of the reference number. This will also list all the documents that DEA received with the permit application.
  2. Applicants then need to pay the permit application fee and give DEA proof of this payment. The completed permit application will then be submitted to the National Bioprospecting Advisory Committee who will assist the issuing authority to evaluate the benefit-sharing agreements and bioprospecting permit applications.
  3. After evaluation by the advisory committee, the permit application will either be returned to the applicant for further clarity and information or forwarded to the Minister for a final decision.
  4. The Minister will then either approve the benefit-sharing agreement and material transfer agreement and instruct the permit to be issued, or decline the application. If successful, the Director-General of DEA will issue the bioprospecting permit. If unsuccessful, there is opportunity to appeal this decision.

- **What can be considered confidential if the agreement is published?**

  The Promotion of Access to Information Act is the main law regulating confidentiality although the BABS Regulations also include a definition of 'confidential information' (see Regulator Guidelines). It is important to note that a balance must be struck between protecting confidential information and providing sufficient information to enable members of the public to submit meaningful representations or objections.

- **What is the National Bioprospecting Advisory Committee? And what role does it play in ABS?**

  The Bioprospecting Advisory Committee consists of representatives from the South African National Biodiversity Institute (SANBI), South African National Parks (SANParks), provincial nature conservation agencies, as well as representatives from various national government departments including the departments of environment, agriculture, forestry and fisheries, science and technology, health, and trade and industry. This expert group acts as a panel which advises the issuing authority on matters related to bioprospecting, access and benefit sharing. It also offers its combined expertise in evaluating benefit-sharing agreements, thereby enabling the Minister to make an informed decision when considering the approval of agreements and permit applications.

- **What can be done in the event of a dispute arising?**

  Disputes between parties to a benefit-sharing agreement are contractual disputes that can be settled through the courts. However, this is expensive and time consuming. An alternative option is to include a provision in the agreement that either party can refer a dispute to mediation, and if that fails, to arbitration. If an agreement includes a provision like this, it must also say how the mediator and arbitrator will be appointed, in case the parties cannot agree on a person to mediate or arbitrate. It is important to stipulate in the agreement who would be responsible for costs should a dispute arise.

- **What must you do with any money that is due to stakeholders?**

  Money due to stakeholders must be paid into the Bioprospecting Trust Fund. The Director General of the DEA will then disburse the funds to the stakeholders, according to the provisions in the benefit-sharing agreement.

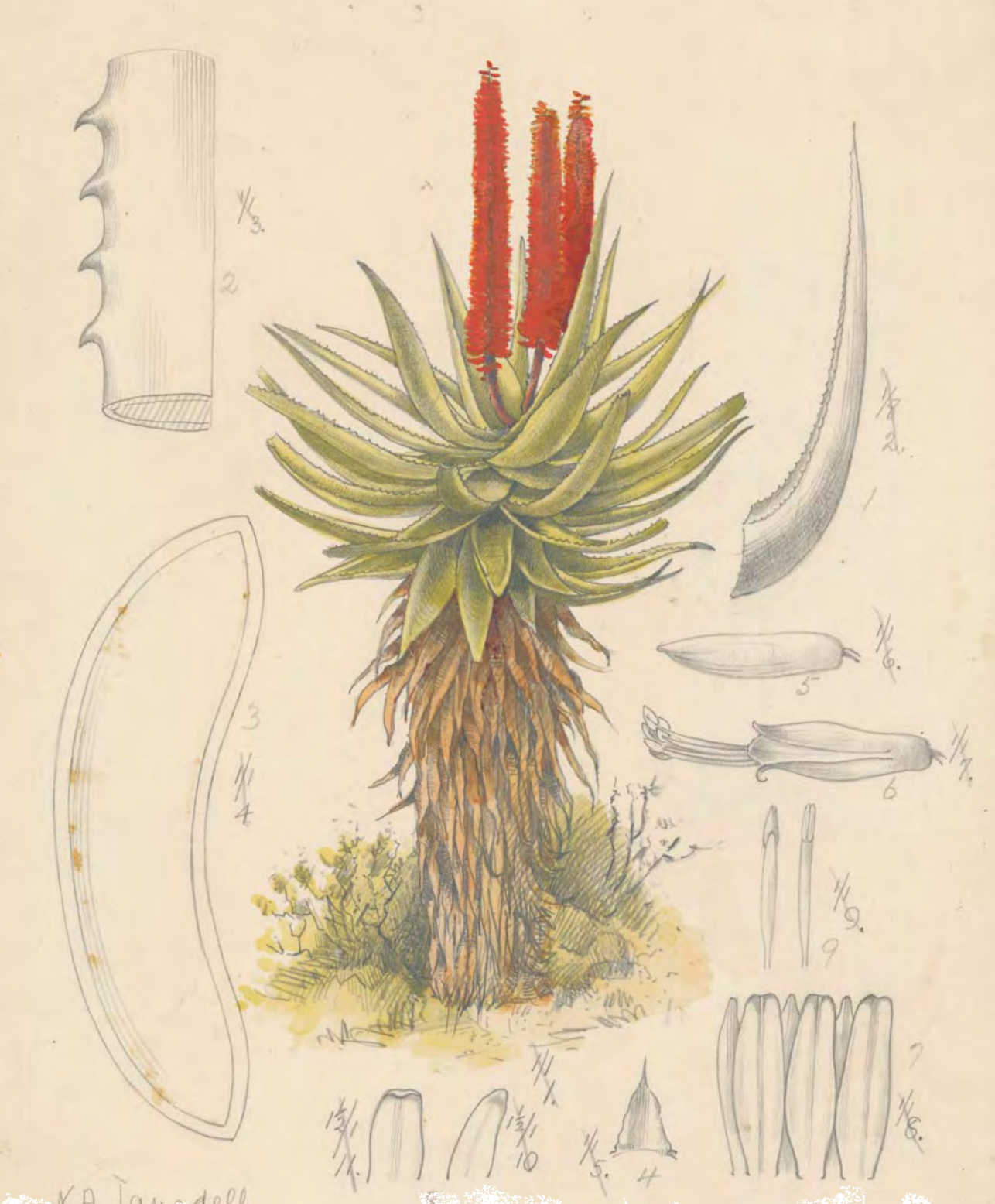
- **Can a benefit-sharing agreement be reviewed?**

  The standard benefit-sharing agreement in Annexure 8 of the BABS Regulations allows for the agreement to be reviewed. Parties to the benefit-sharing agreement will need to agree on when and how frequently this should take place. The user is expected to provide any new material information to providers at least a month before the agreement is reviewed, to enable providers to make informed decisions.

The benefit-sharing agreement should specify intervals at which the user will report to the provider of the indigenous biological resource or traditional knowledge on the status of the bioprospecting project and related benefits. It may be useful to include in the contract the manner, place and medium through which the user will provide status updates. It should be borne in mind that information may have to be translated or simplified in order to be accessible for providers.

3.9 What kind of benefits can be negotiated?

The types of benefits that are negotiated with providers of biological resources or traditional knowledge will vary widely according to local conditions and the nature of the company or institute accessing the resource or knowledge. A benefit-sharing agreement is a legal requirement for the commercialisation phase only, but it is good practice to negotiate benefits for both pure research and bioprospecting discovery phase research. Users and providers are free to negotiate any benefit-sharing arrangement – it is then up to the Minister to decide whether the agreement is fair to all parties. It is important to remember that benefits may differ in terms of scope and duration, and different users are likely to offer very different types of benefits. For example, an academic institute may offer scholarships and other forms of student/educational support, whereas a commercial company could offer royalties or licence fees. There is often an emphasis placed on monetary benefits, whereas non-monetary benefits may in fact deliver more durable benefits – especially in the case where capacity building or technology transfer has taken place. See **APPENDIX 3: BENEFIT-SHARING OPTIONS**, for a list of short-, medium- and long-term monetary and non-monetary benefits which may be offered to providers.



***Aloe ferox* (bitter aloe)** *Source: South African National Biodiversity Institute*

Section 4

Guidelines for regulators of bioprospecting using indigenous biological resources and associated traditional knowledge

Planting *Pelargonium sidoides* *Source: Ulrich Feiter*

4. Regulators

4.1 Introduction

These Regulator Guidelines set out how government will review and assess bioprospecting permit applications. They also provide guidance on the role of officials in assisting parties to negotiate and conclude agreements and set out how benefit-sharing agreements will be evaluated. The guidelines aim to enhance understanding about mandatory legal requirements of the Biodiversity Act, the BABS Regulations and other relevant laws as well as processes and conditions that are discretionary.

These **Regulator Guidelines:**

- provide an overview of the different activities, permits and issuing authorities and describe the circumstances in which a permit is needed;
- explain public law considerations that should be taken into account when making decisions;
- explain public law considerations that should be taken into account when dealing with public participation processes and confidential information;
- present criteria that can be used to verify beneficiaries and traditional knowledge holders identified in benefit-sharing agreements;
- describe some of the factors to consider when assessing benefit-sharing agreements and how benefits have been apportioned;

- identify how to assess whether there has been prior informed consent; and
- explain resource sustainability considerations that need to be integrated into decision-making.

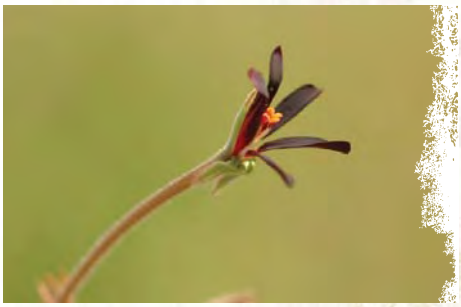
4.2 Distinguishing between different activities, permits and issuing authorities

The first thing that officials need to consider when receiving an application is the type of activity being proposed, and therefore the type of permit that is required. **TABLE 2** gives an overview of permit requirements for bioprospecting and research. There are normally two phases to a bioprospecting project – **the discovery phase** and **the commercialisation phase**. These phases are defined in the Biodiversity Act and the BABS Regulations (see Glossary, **APPENDIX 2**). A 2009 amendment to the Biodiversity Act requires those involved in the discovery phase to notify the Minister of these activities but no longer requires a permit to be obtained.

The utilisation of indigenous biological resources is regulated as follows:

- If **bioprospecting is in the discovery phase** it is necessary to notify the Minister of Water and Environmental Affairs but no permit is required.
- The **export of indigenous biological resources for the discovery phase of bioprospecting** is covered by the BABS Regulations and an integrated export and bioprospecting permit (issued by DEA) is required.
- If the activity is in the **commercialisation phase of bioprospecting**, a bioprospecting permit is required. A permit will still be required from the relevant provincial authority or authority with jurisdiction before the harvesting or collection of indigenous biological resources is allowed.
- If there is **intended export of indigenous biological resources for the commercialisation phase of bioprospecting**, DEA is the issuing authority and an integrated export and bioprospecting permit is required. A permit will still be required from the relevant provincial authority or authority with jurisdiction before the harvesting or collection of indigenous biological resources is allowed.
- **Research other than bioprospecting** only requires a permit under the BABS framework if it is being exported. The relevant MEC is the issuing authority for these export permits. Applicants will also still need a collection and/or research permit from the relevant provincial authority depending on the provincial legislative requirements. A listed Threatened or Protected Species (TOPS) or a CITES-listed species may be exported with an integrated BABS/CITES or BABS/TOPS export permit, or separate BABS/TOPS/CITES permits.

Harpagophytum procumbens **in flower** *Source: Ulrich Feiter*



Pelargonium sidoides **flower** *Source: Ulrich Feiter*

BOX R

IDENTIFYING WHETHER A PERMIT IS REQUIRED

It may be difficult to determine whether or not a permit is required and officials will need to apply the definition of 'commercialisation' and the exemption provisions. In summary, it is not necessary to apply for a permit under this legislation for:

- research other than bioprospecting, unless the resources are being exported;
- resources that are not indigenous biological resources (see definition in section 2 read with section 80(2) of the Biodiversity Act);
- the discovery phase of a bioprospecting project being conducted in South Africa (see the definition of 'discovery' and 'commercialisation' in section 2 of the Biodiversity Act and in BABS Regulation 1); or
- anything that has been exempted under the exemption notice issued by the Minister.[2]

TABLE 2

AN OVERVIEW OF PERMIT REQUIREMENTS FOR BIOPROSPECTING AND RESEARCH[3]

ACTIVITY	TYPE OF PERMIT	RELEVANT LAW	ISSUING AUTHORITY
Nationally (in South Africa)			
Research other than bioprospecting conducted in South Africa	This does not need a bioprospecting permit, but may need a collection and/or research permit from the relevant authority	Exemption notice	Relevant province or government agency with jurisdiction or land ownership (e.g. SANParks, SANBI, Department of Public Works)
Bioprospecting (discovery phase)	None required – notification procedure	NEMBA and BABS Regulations	Notify Minister using prescribed form
Bioprospecting (commercialisation phase)	Bioprospecting permit	NEMBA and BABS Regulations	Minister
Internationally (outside South Africa)			
Export for research other than bioprospecting	Export permit	TOPS/CITES and BABS Regulations	MEC
Export for bioprospecting (discovery phase)	Integrated export and bioprospecting permit	NEMBA and BABS Regulations	Minister
Export for bioprospecting (commercialisation phase)	Integrated export and bioprospecting permit	NEMBA and BABS Regulations	Minister

The Minister refers to the Minister of Water and Environmental Affairs. The MEC refers to the Member of the Executive Council of a province who is responsible for the conservation of biodiversity in that province.

2 *Government Gazette* No. 30739 No. R 149 (8 February 2008).

3 *Government Gazette* No. 33361 (7 July 2010).

4.3 The importance of considering public laws

There are several laws outside of the Biodiversity Act and BABS Regulations that are relevant for the way in which decisions are made and the public is involved. These include laws related to administrative decision making, access to information, confidentiality and public participation. This section provides an overview of key aspects of these laws, and their relevance for bioprospecting, access and benefit sharing.

4.3.1 Public law considerations for decision making

Decisions by the Minister to approve an agreement and decisions by an issuing authority to grant a permit are administrative decisions subject to the Promotion of Administrative Justice Act (Act No. 3 of 2000) (PAJA). Decisions that are made need to be sufficiently robust to prevent them being overturned by a court. This means that they must comply with the legislative framework, that the correct procedure must be followed and that the decision taken must be reasonable.

The Promotion of Administrative Justice Act

Section 33 of the Constitution provides that everyone has the right to administrative action that is lawful, reasonable and procedurally fair and any person whose rights have been adversely affected by administrative action has the right to be given written reasons.

The right to fair administrative action has been codified in PAJA which defines an administrative act of an organ of state as a decision, or failure to take a decision, that adversely affects the rights of any person and that has direct external legal effect. Section 88(3) of the Biodiversity Act provides that decisions by an issuing authority to issue or refuse a permit must be consistent with PAJA. Other decisions that may be subject to PAJA include:

- a decision by the Minister to appoint an appeal panel and the composition of that panel (section 95 (1)(a));
- an appeal decision by the Minister, the MEC, or an appeal panel; and
- a decision to renew or amend a permit.

The requirements of PAJA

An administrative decision must be lawful

To be lawful, an administrative decision must:

- be made by a person authorised by statute to make the decision or authorised by a valid delegation to make the decision; and
- give effect to the general purpose of the authorising statute.

The delegation of the powers of the Minister and of MECs is regulated by sections 42 and 42A of the National Environmental Management Act, Act No. 107 of 1998 (NEMA). These sections apply to the Biodiversity Act. Under section 42 of NEMA the Minister has delegated the power to issue bioprospecting permits, and integrated export and bioprospecting permits to the Director-General. The power to approve benefit-sharing agreements and material transfer agreements has not been delegated.

Section 6 of PAJA provides that a court may judicially review a decision if a mandatory and material procedure or condition prescribed in an empowering provision was not complied with or if the action was materially influenced by an error of law.

An administrative decision must be reasonable

For a decision to be reasonable, there must be a rational connection between the decision and the information before the decision maker and there must be a rational connection between the purpose of the empowering provision and the decision. Section 6 of PAJA provides that a court may judicially review a decision if "irrelevant considerations were taken into account or relevant considerations were not considered". A judicial review under PAJA is not the same as an appeal. A court will not ask whether it would have made the same decision as the decision maker. Instead, it will ask whether the decision was reasonable in the circumstances. Generally a court will not intervene in an official's decision if the court is satisfied that the official:

- took into account all relevant factors;
- struck a reasonable balance between the different factors; and
- selected reasonable means to pursue the identified legislative goal in the light of the facts.

This means that the reasons for decisions of the Minister to approve or not approve an agreement and the reasons for decisions by issuing authorities to issue or not issue permits must be set out in a way that shows that all relevant information was taken into account. The recommendation that goes to the Minister or issuing authority must provide the Minister or issuing authority with an overview of all relevant information. Information may not be kept from a decision maker if that information is contrary to the recommendation being made. Irrespective of how thorough the process may be at an official level, if the conclusions from that process are not presented in a way that enables a robust decision to be made, a judicial review may be successful.

An administrative decision must be procedurally fair

PAJA provides a framework for procedurally fair administrative actions. The procedural requirements of PAJA are reflected in the Regulations promulgated under the Biodiversity Act. These procedures must be followed.

Other relevant provisions of PAJA

Under section 4 of PAJA an administrator may need to hold an inquiry or run a notice and comment procedure prior to making a decision. This applies where the decision may affect the public.

Under section 5 of PAJA, interested parties have 90 days to request written reasons for a decision, and reasons must be supplied within 90 days of receipt of a request.

Under section 7(2) of PAJA, a person must exhaust all internal remedies before bringing a judicial review – in other words, judicial review is a remedy of last resort. This means that if the legislation makes provision for an appeal procedure, a judicial review can only be brought once those appeal proceedings have been concluded (although the Act does make provision for a court to exempt a person from this requirement in exceptional circumstances and if it is in the interests of justice).

The implications of these provisions are:

- A decision by the Minister to seek public comment on an agreement should comply with section 4 of PAJA.
- Where the Biodiversity Act or BABS Regulations provide that reasons must be given, those provisions rather than the PAJA provisions must be followed. The PAJA provisions will be relevant for decisions under the Biodiversity Act where the Biodiversity Act or the BABS Regulations do not expressly state that reasons must be given. This would apply, for example, to a decision to grant a permit or a decision by the Minister to approve or not approve an agreement.
- A person cannot bring a judicial review of a decision to grant or refuse to grant a permit unless that person has used the appeal procedures set out in section 94 of the Biodiversity Act and in BABS Regulations 14 and 15, and those procedures have been concluded.

4.3.2 Public participation, access to information, and confidentiality

Bioprospecting activities and benefit-sharing agreements are often very controversial. Public interest organisations and communities may be concerned that agreements made are not equitable, that public resources are exploited for private, monopoly gain, or that communities and traditional knowledge holders are unfairly exploited.

The Biodiversity Act makes provision for public participation and the Minister may invite public comment on a benefit-sharing agreement provided no confidential information is made public. In deciding if information is confidential, it is necessary to consider the BABS Regulations which include a definition of 'confidential information' and the Promotion of Access to Information Act, Act No. 2 of 2000 (PAIA).

Importantly, PAIA takes precedence over the BABS Regulations. In other words, if information in an agreement is withheld from the public on the basis of confidentiality, a person may still request that information under PAIA and the test for confidentiality set out in PAIA would have to be considered rather than the test set out in the BABS Regulations. The Minister will therefore use PAIA as a guideline as to what information to publish if he/she intends publishing a benefit-sharing agreement for comment.

Under the BABS Regulations and under PAIA commercial information may be disclosed with the consent of the relevant parties. If the Minister intends publishing a benefit-sharing agreement for comment, a standard form letter should be sent to the parties to the agreement asking if they consent to the whole agreement being published and if they do not consent, asking which provisions they regard as commercially confidential based on the test set out in PAIA.

Under sections 36(1) and 43(1) of PAIA the following information can be withheld:

- trade secrets;
- financial, commercial, scientific or technical information, other than trade secrets, if the disclosure of that information would be likely to cause harm to the commercial or financial interests of a party to the agreement or any other third party;
- information that if disclosed could reasonably be expected to put a party to the agreement at a disadvantage in contractual or other negotiations; and/or
- information about research, the disclosure of which would be likely to expose a party to the agreement or a person carrying out the research or the subject matter of the research to serious disadvantage or to prejudice a party to the agreement in commercial competition.

It is important that a balance is struck between protecting confidential information and providing sufficient information to enable members of the public to submit meaningful representations or objections (which is a requirement of section 100(2)(b) of the Biodiversity Act). While it is the responsibility of the applicant to designate what is confidential, DEA must ensure that this is reasonable and does not preclude effective public involvement.

Any PAIA requests should be sent directly to the Director-General of the DEA.

BOX 5

COMPLIANCE CHECKLIST – MANDATORY PROCEDURAL REQUIREMENTS

Does the decision-maker have the necessary jurisdiction to take the decision? In the case of a bioprospecting project you need to check:

- ✓ that the correct issuing authority has been identified; and
- ✓ whether or not a permit is required.

Before considering the merits of an application, the authority should check that the following formal requirements have been met:

- ✓ the application should be on the prescribed form;
- ✓ the application is in relation to a South African indigenous biological resource, or exotic biological resource modified with South African indigenous biological material;
- ✓ the prescribed application fee should be paid;
- ✓ if required, a benefit-sharing or material transfer agreement should be attached to the form;
- ✓ these agreements should be on the prescribed forms and completed in full;
- ✓ the agreement should provide that any money received as a result of the agreement will be paid into the Bioprospecting Trust Fund; and
- ✓ the applicant (or one of the applicants if it is a joint application) should provide acceptable proof that they are either a South African citizen or permanent resident, or a juristic body registered in South Africa.

4.4 Benefit-sharing and material transfer agreements

Completing the forms

Benefit-sharing and material transfer agreements must be agreed to and approved by the Minister before a bioprospecting permit can be issued. The forms[4] prescribed in the BABS Regulations were designed to give effect to mandatory requirements of the Act and it is therefore critical that the agreements follow the prescribed format and that there is a full and appropriate response to each section of the form.

Determining when material transfer agreements or benefit-sharing agreements are required

- A material transfer agreement and a benefit-sharing agreement are required for all commercial bioprospecting projects when the applicant needs access to the indigenous biological resources from someone else (including an organ of state or a community). You never have a material transfer agreement without a benefit-sharing agreement.
- If the applicant does not need access to the indigenous biological resources (for example, because they are on his or her own property) and is not making use of indigenous knowledge, no agreements are required although a bioprospecting permit is still required.
- If traditional knowledge is involved but the applicant does not need access to the indigenous biological resource, only a benefit-sharing agreement is required.

4 MTA-BABS Regulations Annexure 7; BSA-BABS Regulations Annexure 8.

4.5 Assessing benefit-sharing agreements and apportioning benefits

The decision to grant a permit is a discretionary one. So too is the decision to approve an agreement. In making the decision to approve an agreement, the Minister must be satisfied that the agreement is 'fair and equitable' and fulfils certain prescribed requirements.[5] The term 'fair and equitable' is not defined by the legislation and the meaning must therefore be taken from the context. Some experts believe that the term 'fair' means procedurally fair, and that the term 'equitable' refers to the outcome. Either way, 'fair and equitable' implies fair in all circumstances. This means that the benefits that accrue to some providers may be different from the benefits that accrue to others.

The Minister may consult with any person to provide advice on the agreement and may also invite public comment on whether an agreement is fair and equitable. However, there is no formula that can be used to determine whether the agreement is fair and equitable. Robust benefit-sharing agreements are usually developed through an iterative process, involving comprehensive consultation, transparent negotiations between stakeholders and full disclosure of information. This is a good indicator for a 'fair' agreement. However, agreements also often include highly technical information that may be difficult for non-experts to grasp. The apportioning of benefits that flow from these agreements will depend among other things on:

- the final use of the resource or knowledge;
- the industrial sector that will be commercialising the product;
- the companies involved;
- whether or not intellectual property rights have been granted;
- the degree of exclusivity (whether or not beneficiaries are entering into agreements with other stakeholders, for example);
- the development status of the project;
- the extent to which the product uses traditional knowledge;
- the uniqueness of any knowledge or resource provided;
- the investments already made by users or providers;
- the availability of other similar technologies or products; and
- market drivers.

Financial benefits arising from agreements can take the form of upfront payments, milestone payments (linked to key events such as the filing of a patent or the successful conclusion of a clinical trial), equity investment and royalties. **BOX T** provides more detail about the kinds of benefits that can be expected from different sectors and **BOX U** summarises some of the factors to consider when reviewing royalty ranges. What should be clear is that regulators cannot be expected to become experts about the many facets of natural product development. Advice will need to be sought from those who are involved in the field, but who do not have a vested interest in the outcome of the application. In addition to this expert help there may also be merit in appointing an 'honest broker'[6] to help with negotiations between stakeholders and to ensure that communities are supported to develop fair and equitable agreements.

5 BABS Regulation 17(4).

6 See NEMBA section 82(4)(b); BABS Regulation 10(3)(b) read with BABS Regulation 8(2).

BOX T

ASSESSING IF THE BENEFIT-SHARING AGREEMENT IS FAIR AND EQUITABLE

The nature and form of benefit sharing varies significantly by sector, and is understood quite differently by industry players. In part this is because of variations in the financial profile and research and development process of the industries involved in the commercial use of genetic resources. This has an obvious impact on the scale and nature of benefits that are shared. For example, it is estimated that it takes 10–15 years and costs $802 million to develop a new drug, including the cost of failures. New crops or ornamental varieties are also research intensive. On the other hand, in the biotechnology industry it is not uncommon for the development cycle for a product – such as enzymes for biofuels and detergents – to take one to two years from when a lead enzyme is identified. The risks and investments made in research and development (R&D) play a significant role in determining benefits. These will be unique for each product.

Revenues from commercial products are also dramatically different between sectors, making it difficult to determine a formula for fairness. For instance, more than 105 pharmaceuticals achieved 'blockbuster' status in 2006, with sales greater than $1 billion. Revenue from a single blockbuster drug is greater than the turnover of a company developing a new washing powder from micro-organisms but the risks and associated R&D costs of developing a new drug are also significantly more than those of developing a new washing powder.

Commercialisation chains are also vastly different. In the seed industry the chain of development leading to the final product may not take place within one company. The pharmaceutical industry in contrast typically sells its product directly to consumers. The biotechnology industry may use an organism in an industrial process, but the final product may not include any biological material. All of these different scenarios will involve different strategies for benefit sharing.

BOX U

REVIEWING ROYALTY RANGES

Royalty ranges in benefit-sharing agreement (which in commercial terms are often understood as license agreements) vary significantly depending on the stage of commercialisation and development, the nature of the product, the degree of exclusivity, the extent of territorial rights, anticipated revenues, the extent of R&D investment, the extent the risk is shared between players and the sector involved (e.g. the high risk and high returns of pharmaceutical product versus the low risk and low returns of herbal and complementary medicines). This is complicated by the fact that the value of the product, technology or service is often unknown and is typically very complex to calculate. Finch (2001) proposes a range of royalties for different stages of product development in the biotechnology and pharmaceutical sectors.[7] Royalties of 5–6% of nett sales are often assumed to be the average across many industries. Provider countries may be able to invest more resources and capture additional value when fees are shifted forwards by increasing the upfront collection fee and reducing royalty payments. There is also a lot of evidence to show that if national scientific capabilities are strong, countries will have better negotiating strength in developing fair agreements.

7 Finch, S. 2001. Royalty rates. Current issues and trends. *Journal of Commercial Biotechnology*, Volume 7.

Agree on terms to obtain and use the resource *Source: PhytoTrade Africa*

4.6 Identifying and verifying stakeholders and traditional knowledge holders

Identifying stakeholders

Identifying the correct stakeholders in a benefit-sharing agreement can be extremely challenging.

The Act identifies two categories of stakeholders (section 82):

1. Those who provide **access** to indigenous biological resources.
2. Indigenous communities or individuals whose **traditional use** of the indigenous biological resources or whose **knowledge** of the indigenous biological resources have contributed to (or will contribute to) the bioprospecting.

Identifying and verifying the correct stakeholders

The issuing authority has a statutory duty to protect these stakeholders but it cannot do so unless it is satisfied that the correct stakeholders have been identified. Regulation 8(1)(a) of the BABS Regulations also requires that the correct stakeholders be identified. **It is not the role of the issuing authority to conduct its own investigation but the permit applicant should provide information as to what steps were taken to identify the relevant stakeholders. The issuing authority could also request expert evidence, which will enable it to assess whether the correct stakeholders are protected.**

Stakeholders who provide access to the resources are relatively easy to identify but there are major challenges in identifying the indigenous communities or individuals who use the indigenous biological resources or whose knowledge of these resources contributes to the bioprospecting. The BABS Regulations seek to assist by defining indigenous communities as "any community of people living or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure." However, leadership structure is not defined, and could refer to traditional authorities as well as local government/mayors.

Determining the 'community'?

The definition of community in the South African context is complex and evolving and has been the subject of a number of legal cases which have emphasised the importance of looking at customary and living law and practices that define community membership, including shared rules that determine access to, use of, or benefits from a resource or property right held in common by the group.[8] The definition in the BABS Regulations must be understood broadly in line with this developing jurisprudence. The term 'distinct geographical area' is not limited by current or historical political boundaries (e.g. provincial boundaries or the boundaries of previous homelands) but must be understood in the context of customary systems.

These are very important criteria to consider when determining whether in fact a stakeholder is a 'community' and whether that community has customarily made use of the relevant resources "in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised by them". This may require that the applicant provide expert evidence to verify the status of the community, along with information about the community and evidence that he/she has searched available literature for this information and has made valid attempts to identify, locate and negotiate with legitimate holders of resources or knowledge. The applicant should be asked not only to show that the community has rights or interests in a distinct geographical area but also that there is a genuine history of customary use of the resource, and a legitimate claim to holding traditional knowledge about it.

What happens if more than one community holds traditional knowledge about the resource?

Traditional knowledge about indigenous biological resources is seldom confined to a single group of people, although specialised or unique knowledge may exist among certain individuals or within certain families. More typically, knowledge will be shared among particular communities (e.g. the San) who share a culture but may live in many different regions, or in areas where the resource naturally occurs. These factors need to be taken into consideration when identifying and validating traditional knowledge holders.

Stakeholder rights

Stakeholders have the right to:

- material disclosure of all information relevant to the bioprospecting;
- give or withhold consent;
- the fair and equitable sharing of benefits flowing from the bioprospecting; and
- be informed annually (unless agreed otherwise) if any money due to them in terms of an agreement has been paid into the Bioprospecting Trust Fund, and be paid that money.

If an indigenous community is a stakeholder, that community must:

- authorise one of its members to act as its representative in signing a benefit-sharing agreement; and
- adopt a written resolution confirming that that person has been authorised to enter into the agreement on behalf of the community, that the community has full knowledge of the bioprospecting project and that it consents to entering into the benefit-sharing agreement.

8 See for example, the High Court and Constitutional Court judgements in *Tongoane and Others v Minister for Agriculture and Land Affairs and Others* 2010 (6) SA 214 (CC). The High Court recognised "the layered nature" of communal rights in customary systems including those existing at family, clan, village and group levels. A definition of community must incorporate smaller or independent communities living within the boundaries of larger communities that may have been given substance and form partly through apartheid legislation.

What happens if a stakeholder grants access to resources or knowledge but refuses to engage in a benefit-sharing agreement?

Consent to access resources must be reflected in an agreement. If no agreement is in place, one can assume there is no consent.

Shelling marula *Source: Myles Mander*

4.7 Identifying steps in the prior informed consent process

The Biodiversity Act deals with prior informed consent by requiring, under section 82(2) and (3), that before issuing a permit an issuing authority must be satisfied that:

- all relevant material has been disclosed to stakeholders, including information about the intended end result;
- on the basis of that disclosure the stakeholders have consented to providing access or sharing knowledge;
- material transfer and benefit-sharing agreements have been entered into with those stakeholders; and
- those agreements have been approved by the Minister,[9] who must be satisfied that benefit-sharing agreements are fair and equitable to all parties (see Regulation 17(3)).

Two main questions need to be asked by the issuing authority.

1. Has all necessary information been disclosed to stakeholders?

   The applicant is required by the prescribed form to assert that there has been material disclosure and to substantiate this by listing all material disclosed. The obligation is on the applicant to disclose fully all relevant information.

9 NEMBA sections 83(2) and 84(2)

It is the responsibility of the issuing authority to ensure compliance with the requirement for full disclosure. Follow up is required if DEA has reason to believe there has not been full disclosure.

2. Are there agreements in place that confirm consent and that are fair and equitable with regard to benefit sharing?

Although the Minister must approve the agreements and must be satisfied that they are fair and equitable, the issuing authority must be satisfied that there has been material disclosure and consent.

Both the issuing authority and the Minister could be challenged on their decisions and both must be able to demonstrate that they have applied their minds to the decision and that their decisions were informed by relevant information.

To avoid overlap, facilitate cooperation, and avoid a legal challenge the issuing authority should be responsible for preparing a memorandum to the Minister recommending whether the Minister should approve the agreements. The memorandum should confirm whether the issuing authority is satisfied that there has been material disclosure and prior informed consent and the Minister should only approve an agreement if the issuing authority has confirmed this.

The memorandum to the Minister should:

- confirm that the issuing authority is satisfied that there has been material disclosure and that the relevant stakeholders have provided their consent based on that disclosure. As this is a matter for the issuing authority, rather than the Minister, it will not be necessary to provide extensive detail of the disclosure made or the steps taken to ensure that there has been consent;
- be accompanied by a copy of the agreements submitted by the applicant;
- make a recommendation on whether a benefit-sharing agreement (if applicable) should be approved based on an assessment of whether it is fair and equitable and whether it makes provision for:
  - (a) enhancing the scientific knowledge and technical capacity of persons, organs of state or indigenous communities to conserve, use and develop indigenous biological resources; or
  - (b) any other activity that promotes the conservation, sustainable use and development of the relevant indigenous biological resources;[10]
- make a recommendation on whether the advice of a person 'competent to provide technical advice' should be sought; and
- make a recommendation on whether public comment should be sought on the agreement.

The more controversial an agreement, the more likely it will be challenged and the more information should be provided to the Minister in support of recommendations.

If a permit is refused, the issuing authority must give reasons for that decision in writing. In order to ensure consistency, the memorandum to the Minister or MEC should be the basis for the reasons document. When the Minister or MEC makes a decision they should specifically say the decision is being made for the reasons set out in the memorandum or indicate to what extent they disagree with the memorandum. If a decision is taken on appeal or judicial review, the memorandum to the decision maker and the reasons for the decision will become critical in those further proceedings.

10 See Regulation 17(4) of BABS Regulations.

The appeal process

A decision to grant a permit with or without conditions and a decision to refuse a permit is subject to appeal to the Minister. The Minister may reconsider the application or redirect the appeal to the relevant MEC or to an appeal panel (section 94). Importantly, a decision to renew or amend a permit under section 93A is not subject to an appeal.

An appeal does not suspend the decision unless the Minister or MEC or panel directs otherwise. It is important for an appellant to specify in its appeal if it believes the decision should be suspended.

Calculating time periods

The BABS Regulations refer to time periods as a number of working days. This should be calculated as Monday to Friday, excluding public holidays. The first day is excluded but the last day is included. In other words, if a request for reasons is given, the day the request is received is not counted in the calculation but the day on which the reasons are given is counted.[11] Permits must be issued within a reasonable time.

4.8 Environmental impact, resource sustainability and conservation benefits

There are two key conservation issues that arise in bioprospecting: (1) the sustainability and environmental impacts of harvesting or collection; and (2) the conservation benefits from bioprospecting.

Environmental impact and sustainable use

Although the discovery phase of bioprospecting typically requires only small amounts of samples, the commercial phase may require significant amounts of material to be viable, raising questions about over-harvesting and environmental impact.

Sustainable use is a central issue to consider and a permit can be withheld if it cannot be shown that:

- the impact on the environment of granting the permit will be negligible or will be minimised and remedied; or
- the activity will not deplete the resource beyond a level where its integrity is jeopardised.

Applicants will also need to consult with relevant provinces to determine maximum sustainable yields and harvesting protocols for some species and will need to obtain collection permits from provincial authorities or other landowners. In deciding whether to grant a collection permit, the normal considerations of the relevant authority will apply. A provincial authority will not be bound to grant a collection permit because a bioprospecting permit has already been issued. Both national and foreign issuing authorities may also require the applicant to provide at the expense of the applicant an independent risk assessment or expert evidence as the issuing authority may determine.[12]

Conservation benefits

A key argument in favour of bioprospecting is that the use of biodiversity can create an economic incentive to conserve the resource.

In order to conserve the resource, meaningful benefits need to be allocated back to conservation from bioprospecting – ideally to support the ecosystem from where the resource was extracted, or the

11 See section 4 of the Interpretation Act, Act No. 33 of 1957.

12 NEMBA section 89; BABS Regulations 7(2)(a) and (b); 7(5)(b) and (c).

species used, or to protect the species from being over-exploited. These benefits may be monetary but can also take the form of non-monetary benefits such as taxonomic information, training, specimen deposits and knowledge generation. It is important to ensure that conservation benefits are built into benefit-sharing agreements so that a 'win-win' situation evolves.

4.9 Issuing the permit

Before granting a permit, an issuing authority must be satisfied with a number of substantive issues and, if not, has the discretion to request:

- further information (section 88 of the Biodiversity Act and Regulations 7(5)(b) and (c) of the BABS Regulations); and/or
- that a risk assessment be carried out, or expert evidence be given (section 89 of the Biodiversity Act).

If the issuing authority is unable to satisfy itself on the basis of information submitted, it should exercise its discretion to request further information or evidence under these sections before it makes a decision. Making a decision not to grant a permit because of inadequate information may be reviewable if the issuing authority has not given the applicant the opportunity to provide further information. It is not necessary for the issuing authority to carry out these further investigations itself. Additional information should be provided by the applicant, at the applicant's cost.

An issuing authority may not issue a permit unless it is satisfied that:

- the interests of stakeholders are protected;
- all material information has been disclosed to stakeholders and their informed consent has been obtained (section 82(2) of the Biodiversity Act and BABS Regulation 8(1));
- the impact on the environment of granting the permit will be negligible or will be minimised and remedied (Regulation 7(2)(a));
- the activity will not deplete the resource beyond a level where its integrity is jeopardised (Regulation 7(2)(b));
- in addition, under Regulations 12 and 13 of the BABS Regulations "the export will be for a purpose that is in the public interest, including:

  (a) the conservation of biodiversity in South Africa;

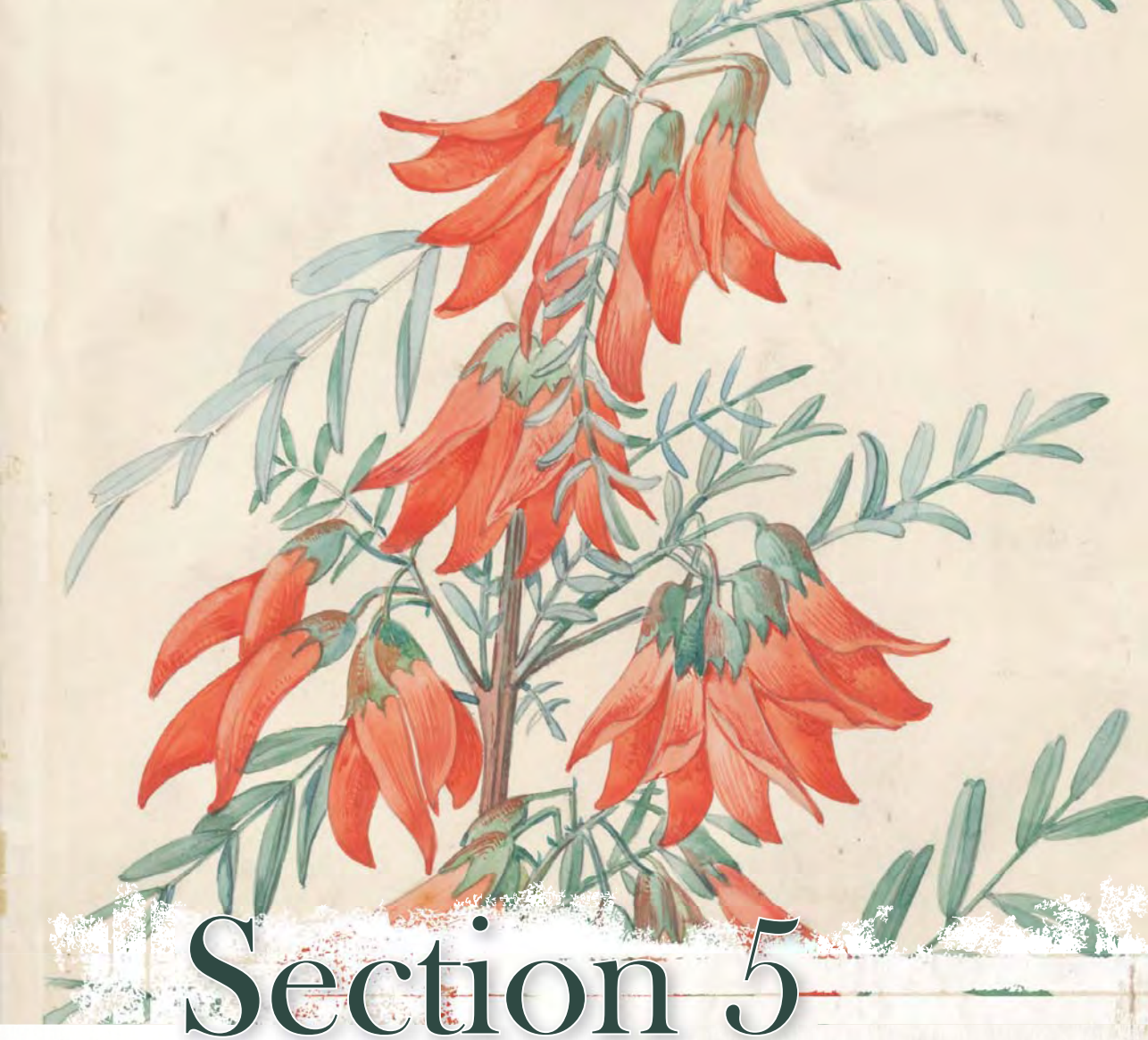
  (b) the economic development of South Africa; or

  (c) enhancing the scientific knowledge and technical capacity of South African people and institutions."

The Bioprospecting Trust Fund

Once benefit-sharing agreements are approved, all money arising from these agreements must be paid into the Benefit-Sharing Trust Fund. This is also the Fund from which all payments to stakeholders will be made. It is important to note that this is not a discretionary fund but instead serves as a 'bank account' to transfer money to stakeholders. There is no administrative charge, and payments are made strictly within the terms of the benefit-sharing agreement.

The Bioprospecting Trust Fund is very different from a Community Trust Fund that may be established to distribute benefits at a local level. For example, a community could establish a Trust Fund to distribute benefits from benefit-sharing agreements. This Trust Fund should have its own trustees, and its own rules for distributing benefits. Money from any approved benefit-sharing agreement would be channelled from the Bioprospecting Trust Fund to the community Trust Fund. The Bioprospecting Trust Fund would simply transfer this money to the community without playing any role in determining how this money would be distributed or used.



Section 5

Appendices

Appendix 1: Acronyms and abbreviations

ABS	access and benefit sharing
BABS	Bioprospecting, Access and Benefit Sharing
BMP	Biodiversity Management Plan
BSA	benefit-sharing agreement
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
DAC	Department of Arts and Culture
DAFF	Department of Agriculture, Forestry and Fisheries
DEA	Department of Environmental Affairs
DOH	Department of Health
DST	Department of Science and Technology
DTI	Department of Trade and Industry
GMO	genetically modified organism
IBR	indigenous biological resource
IKS	indigenous knowledge system
IPR	intellectual property right
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	mutually agreed terms
MLRA	Marine Living Resources Act (No. 18 of 1998)
MTA	material transfer agreement
NEMA	National Environmental Management Act (No. 107 of 1998)
NEMBA	National Environmental Management: Biodiversity Act (No. 10 of 2004)
NGO	non-governmental organisation
NIKSO	National Indigenous Knowledge Systems Office
OC	Oceans and Coasts
PAIA	Promotion of Access to Information Act (No. 2 of 2000)
PAJA	Promotion of Administrative Justice Act (No. 3 of 2000)
PIC	prior informed consent
R&D	research and development
SANBI	South African National Biodiversity Institute
SANParks	South African National Parks
TK	traditional knowledge
TOPS	threatened or protected species
TRIPS	Trade-Related Intellectual Property Rights Agreement
UEBT	Union for Ethical Biotrade
WIPO	World Intellectual Property Organization

Appendix 2: Glossary of terms

Access – Access to biological resources is not defined in the CBD, the Biodiversity Act or BABS Regulations. Its ordinary meaning in the context of biodiversity use relates to acquiring indigenous biological resources or traditional knowledge for the purposes of bioprospecting or any other kind of research.

Benefit – Bioprospecting activities may give rise to various benefits. These could be either monetary or non-monetary in nature.

Benefit-sharing agreement – An agreement in the form of Annexure 8 of the BABS Regulations, concluded between a permit applicant and a stakeholder. The agreement provides for sharing by the stakeholder in any future benefits that may be derived from the bioprospecting to which the application relates.

Bioprospecting – Relates to any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation.

Bioprospecting permit – A permit, issued in terms of section 88 of the Biodiversity Act, to engage in the commercialisation phase of a bioprospecting project

Bioprospecting Trust Fund – This is the Fund established by section 85(1) of the Biodiversity Act (BABS Regulations). All money arising from benefit-sharing agreements and due to stakeholders must be paid into the Fund. (See Trust Fund below.)

Biological diversity – or **Biodiversity** means 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 (Biodiversity Act and CBD).

Biopiracy – A term used to describe the way in which corporations or researchers misappropriate biological resources or traditional knowledge through the patent system. It can also refer to the unauthorised collection for commercial purposes of biological resources or traditional knowledge.

Biotrade – Used to describe any activity relating to the commercial collection, processing and sale of products derived from biodiversity. When described as BioTrade it is often linked to criteria of environmental, social and economic sustainability.

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Bonn Guidelines) – These voluntary guidelines, adopted in 2002, aim to clarify provisions on ABS contained in the CBD. They provide guidance for drafting national legislation and for negotiating ABS agreements in the absence of national legislation.

Commercialisation phase of bioprospecting – The phase in bioprospecting where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is sufficiently established to begin the process of commercialisation. Activities seen as 'commercialisation' may include the filing of intellectual property, commencing clinical trials and product development, or the multiplication of indigenous biological resources (National Environmental Laws Amendment Act (No.14 of 2009) and BABS Regulations).

Convention on Biological Diversity (CBD) – An international treaty, signed in Rio de Janeiro, 1992 at the United Nations Conference on Environment and Development. The CBD guarantees individual states sovereign rights over their biodiversity resources and the pattern of their utilisation and comprises three main objectives: the conservation of biological diversity, sustainable use of its components, and the fair and equitable sharing of the benefits arising from the use of genetic resources. Currently the number of parties to the Convention totals 193 states and the European Community.

Derivative – Any part, tissue or extract, of an animal, plant or other organism. It may be fresh, preserved or processed, and includes any chemical compound derived from such part, tissue or extract.

Discovery phase of bioprospecting – Any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is not sufficiently clear or known to begin the process of commercialisation (National Environmental Laws Amendment Act).

Ecosystem – A dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit (Biodiversity Act).

Export – Taking out or transferring from a place within the Republic of South Africa to another country or to international waters (Biodiversity Act).

***Ex-situ* conditions** – The maintenance of components of biological diversity outside their natural habitats, for example in gene banks, seed banks, culture collections, museums and herbaria.

Genetic material – Any material of plant, animal, microbial or other origin, containing functional units of heredity (Biodiversity Act).

Genetic resource – any genetic material, or the genetic potential or characteristics of any species (Biodiversity Act).

Habitat – A place where a species or ecological community naturally occurs (Biodiversity Act).

Indigenous biological resource – Any living or dead animal, plant or other organism of an indigenous species, including any derivative or genetic material of any indigenous species.

Includes –

- any indigenous biological resources indigenous biological resources gathered from the wild or accessed from any other source, including any animals, plants or other organisms of an indigenous species that are cultivated, bred or kept in captivity or cultivated or altered in any way by means of biotechnology;
- any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms referred to in sub paragraph (i); and
- any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the use of biotechnology, have been altered with any genetic material or chemical compound found in any indigenous species or any animals, plants or other organisms referred to in subparagraph (i) or (ii); but

(b) **excludes –**

(i) genetic material of human origin;

(ii) any exotic animals, plants or other organisms, other than exotic animals, plants or other organisms referred to in paragraph (a)(iii); and

(iii) indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture.

Indigenous community – Any community of people living or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure and –

- whose traditional uses of the indigenous biological resources to which an application for a permit relates, have initiated or will contribute to or form part of the proposed bioprospecting; or
- whose knowledge of or discoveries about the indigenous biological resources to which an application for a permit relates are to be used for the proposed bioprospecting (BABS Regulations).

Indigenous species – any species that occurs, or has historically occurred, in a free state in nature within the borders of South Africa. It excludes any species that has been introduced to South Africa as a result of human activity.

Indigenous use or knowledge – Includes knowledge of, discoveries about or the traditional use of indigenous biological resources, if that knowledge, discovery or use has initiated or will contribute to or form part of a proposed bio-prospecting or research project to which an application for a permit relates (BABS Regulations). (See also traditional use or knowledge, below.)

***In-situ* conditions** – Conditions where biological resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) – This treaty was adopted by the Food and Agriculture Organisation in 2001. Its objectives are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising out of their use. Through use of a standard material transfer agreement it sets up a multilateral system to facilitate access to these resources and ensure fair benefit sharing.

Material Transfer Agreement (MTA) – An agreement in the form of Annexure 7 of the BABS Regulations between an applicant for a permit and a person, including any organ of state or community, providing or giving access to the indigenous biological resources to which the application relates.

Milestone payment – Payment made at a significant new development or stage in a bioprospecting agreement.

Mutually agreed terms (MAT) – 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.

Patent – A form of intellectual property protection available for inventions that are new, involve an inventive step and are capable of being used in trade, industry or agriculture (Patents Act No. 57 of 1978).

Prior art – The existing knowledge base before an invention was discovered, or before an invention was disclosed by filing a patent application. In order to protect their traditional knowledge from perceived biopiracy, some communities have created traditional knowledge databases to record their traditional knowledge as prior art.

Prior informed consent (PIC) – Prior informed consent is not defined within the CBD, but the key elements are commonly identified as:

- **prior** – before access to knowledge or biological resources takes place;
- **informed** – based on truthful disclosure of information about the use that will be made of the knowledge or biological resources that is adequate to understand the implications; and
- **consent** – the explicit consent of the government and/or stakeholders or knowledge or rights holders.

Thus, prior informed consent is an approval in advance for the use of biological resources and/or any associated traditional knowledge based on adequate information disclosure.

Provider country – The country supplying biological resources collected from *in-situ* sources, including populations of both wild and domesticated species or taken from *ex-situ* sources which may or may not have originated in that country.

Public domain information – The information and knowledge already available in published or other forms; the realm of publications, inventions and processes that are not protected by copyright or patents.

Royalty – Royalties are usage-based payments made by one party to another for ongoing use of an asset, sometimes an intellectual property. Royalties are typically agreed upon as a percentage of gross or net revenues derived from the use of an asset or a fixed price per unit sold of an item.

Species – A kind of animal, plant or other organism that does not normally interbreed with individuals of another kind, and includes any sub-species, cultivar, variety, geographic race, strain, hybrid or geographically separate population (Biodiversity Act).

Stakeholder – According to the Biodiversity Act, a stakeholder means a person, an organ of state or a community that provides access to indigenous biological resources, or an indigenous community or a specific individual whose traditional use, knowledge of or discoveries of any indigenous biological resource initiated, will form part of, or are to be used for the proposed bioprospecting.

Sustainable use – The use of an indigenous biological resource in a way and at a rate that would not lead to its long-term decline, would not disrupt the ecological integrity of the ecosystem in which it occurs and would ensure its continued use to meet the needs and aspirations of present and future generations of people (Biodiversity Act).

Traditional use or knowledge – 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, and includes discoveries about the relevant indigenous biological resources by that community (BABS Regulations).

Trust fund – An amount of capital which a person places in custody of a trustee to be administered for the benefit of another (the beneficiary).

Appendix 3: Benefit-sharing options

(Sourced from the Bonn Guidelines, the Nagoya Protocol and Annexure 8 of the BABS Regulations)

SHORT-TERM BENEFIT-SHARING OPTIONS
Up-front payments
Information
Species inventories
Acknowledgement of parties giving access to resources
Voucher specimens with national institutions
Access to international collections by South Africans
Copies of photographs and slides
Simplified and popularised posters, manuals, pamphlets and other documents translated into local languages
Fees paid per sample collected
MEDIUM-TERM BENEFIT-SHARING OPTIONS
Access fees
Other fees – such as for consultation, use of facilities and infrastructure
Milestone payments
Salaries of community members employed by the company – e.g. as assistants and guides
Mutually agreed preferential terms
Environmental education
Research funding
Sharing of research and development results
Access to research data
Copies of proposals, reports and publications provided
Collaboration, co-operation and contribution in scientific research and development programmes – e.g. by including local assistants, guides and informants in the research process
Ongoing communication of bioprospecting objectives, methods and findings, translated into local languages
Student training and support
Training related to biological resources
Training of local people as appropriate in relevant scientific, legal and management issues
Collaboration, co-operation and contribution in education and training
Access to and transfer of technology and knowledge, particularly related to the biological resource
Strengthening capacity for technology transfer
Equipment and infrastructure support
Human and material resources to strengthen capacity for the administration and enforcement of access regulations
Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies

LONG-TERM BENEFIT-SHARING OPTIONS
Social recognition
Licence fees in case of commercialisation
Payment of royalties
Special fees paid into trust funds supporting conservation and sustainable use of biodiversity
Joint ventures
Supply contracts
Co-ownership of relevant intellectual property rights
Co-authorship of publications
Participation in product development
Institutional capacity building
Contributions to the local economy – e.g. grants for development and environmental education projects
Community development projects
Admittance to *ex-situ* facilities of biological resources
Admittance to databases
Recognition and promotion of traditional knowledge/use

Appendix 4: An example of a community resolution

RESOLUTION OF THE KARAMAKA COMMUNITY INHABITING THE MASUNGA AREA, MPUMALANGA PROVINCE, SOUTH AFRICA

It is hereby recorded that on *7 February 2010*, representatives of the *Karamaka* community met at the Masunga Community Centre. At this meeting, the bioprospecting project relating to the transfer of the Tapoca plant and the use of the associated traditional knowledge was discussed.

At this meeting, it was resolved that:

1. We are the *Karamaka* community, holders and owners of traditional knowledge/indigenous biological resources relating to the Tapoca plant.
2. We have full knowledge of the bioprospecting project wherein Leipzig Botanic Research Institute wants to use the Tapoca plant and our traditional knowledge about the Tapoca plant for the specific purpose of researching the medicinal properties of the Tapoca plant only.
3. We jointly agree to share our the Tapoca plant and our traditional knowledge with Leipzig Botanic Research Institute for the purpose mentioned in 2 above.
4. We authorise .....*[name of person and ID number]*....., *[further description – eg.: the chairperson of the Executive Committee of the community]*....., to represent us.
5. This authorisation is for the agreement with .....*[name of company/research institution]*....., for the purpose stated above, and does not relate to any other agreement.
6. This resolution will be signed by .....*[number of members signing the resolution]*..... members of our community, namely: .....*[names and ID numbers of chosen members]*..... or *[the Executive Committee, as the case may be]*..... on our behalf.

Signed at .....*[place]*..... **on this** .....*[date]*..... **day of** .....*[month]*..... **20**.....

Full Names: .....
Duly representing the..... Community

Full Names: .....
Duly representing the..... Community

[Make provision for the number of members signing this resolution]

Appendix 5: Key legislation relevant to access and benefit sharing

POLICY/LAW/BILL/ REGULATION	CONTENT and WEBLINK	RESPONSIBLE INSTITUTIONS
POLICIES		
Indigenous Knowledge Systems Policy	The IKS Policy identifies various means of protecting indigenous knowledge in the South African context. These include the intellectual property system, databases, *sui generis* laws (laws of a special kind) and registers. http://www.dst.gov.za/images/pdfs/IKS_Policy%20PDF.pdf	Department of Trade and Industry (DTI) Department of Science and Technology (DST)
Traditional Medicine Policy	The draft Traditional Medicine Policy provides a framework for the institutionalisation of African Traditional Medicine in South Africa. http://www.info.gov.za/view/DownloadFileAction?id=85969	Department of Health (DOH)
LAWS		
Agricultural Pests Act (No. 36 of 1983)	Provides for the prevention and combating of agricultural pests, and regulates the importation of controlled goods. Prohibits any person from importing into South Africa any plant without a permit. The Minister has imposed a number of controls concerning the import of seeds, for example by requiring phytosanitary certificates. Includes restrictions on the importation of controlled goods, which include among them, plants, pathogens and insects. http://www.nda.agric.za/docs/NPPOZA/Agricultural%20Pests%20Act.pdf	Department of Agriculture, Forestry and Fisheries (DAFF)
Animal Improvement Act (No. 62 of 1998)	Provides for the breeding, identification and utilisation of genetically superior animals in order to improve the production and performance of animals. http://www.info.gov.za/view/DownloadFileAction?id=70720	DAFF
Conservation of Agricultural Resources Act (No. 43 of 1983)	Provides for the conservation of agricultural resources. New regulations introduce strict controls for invading plant species. http://cer.org.za/virtual-library/conservation-of-agricultural-resources-act-1983/	DAFF and provincial departments of agriculture
Constitution of the Republic of South Africa (No. 108 of 1996)	Conservation and ecological sustainability are given prominence in the Bill of Rights. The Constitution does not vest ownership of genetic resources in the State. http://www.info.gov.za/documents/constitution/1996/a108-96.pdf	Both national and provincial government are responsible for most functions relevant to biodiversity, but national parks, botanical gardens, and marine resources are exclusively a national competence
Customs and Excise Act (No. 91 of 1964)	Provides for the prohibition and control of the importation, export or manufacture of certain goods. http://www.vertic.org/media/National%20Legislation/South_Africa/ZA_Customs_Excise_Act_1964.pdf	Department of National Treasury
Genetically Modified Organisms Act (No. 15 of 1997) Amendment Act (No. 23 of 2006)	Controls the development, production, use and application of genetically modified organisms (GMOs). http://www.info.gov.za/acts/1997/act15.htm The GMO Amendment Act gives effect to the Cartagena Protocol and amends components of the Act relating to its institutions, permit application processes, risk assessments and liability. http://www.info.gov.za/view/DownloadFileAction?id=67850	DAFF. Establishes an Executive Council as the main decision-making forum, and an Advisory Committee to provide expert input

POLICY/LAW/BILL/ REGULATION	CONTENT and WEBLINK	RESPONSIBLE INSTITUTIONS
Intellectual Property Rights from Publicly Financed Research and Development Act (No. 51 of 2008)	The Act applies strictly to intellectual property created with public funds. Provisions stipulate that institutions that create intellectual property with public funds will own the intellectual property, regardless of what may have been agreed between the parties. In terms of the Act, the private entity may only become a co-owner of the intellectual property if, inter alia, there is joint creatorship of intellectual property, or appropriate arrangements are made for sharing benefits with the intellectual property creators. http://us-cdn.creamermedia.co.za/assets/articles/attachments/18804_act_51-08.pdf	DST
Patents Act (No. 57 of 1978)	The purpose of the Act is to provide for the registration and granting of patents for inventions and for matters connected therewith. Provides for the patenting of micro-organisms and microbiological processes but prohibits the patenting of plants and animals. http://www.cipro.co.za/legislation%20forms/patents/patent%20act.pdf	DTI
Patents Amendment Act (No. 20 of 2005)	Amends the Patents Act 57 of 1978 so as to require an applicant for a patent to furnish information relating to the use of indigenous biological resources or traditional knowledge in an invention. http://www.info.gov.za/view/DownloadFileAction?id=67873	
Plant Breeders Rights Act (No. 15 of 1976)	Provides a system for the protection and registration of the rights of certain breeders to prescribed varieties of plants. The Act includes the notion of 'farmers' privilege' for seed-saving but does not provide for farmers' rights. http://www.vonseidels.co.za/downloads/Plant%20Breeders%20Rights%20Act%20No.%2015%20of%201976.pdf	DAFF
Plant Improvement Act (No. 53 of 1976)	Provides a framework for the sale of certain plants and the cleansing, packing and sale of certain propagating material. http://www.nda.agric.za/docs/plant_improvement/default.htm	DAFF
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. http://www.info.gov.za/view/DownloadFileAction?id=70675	OC branch of the DEA
National Environmental Management Act (No. 107 of 1998) (NEMA)	Gives legal effect to the Constitution and to the White Paper on Environmental Management Policy. Sets in place procedures and mechanisms for cooperative governance and regulates environmental impact assessments. http://www.info.gov.za/view/DownloadFileAction?id=70641	DEA is the lead agent
National Environmental Management (NEM): Biodiversity Act (No. 10 of 2004)	Provides for the management and conservation of South Africa's biodiversity within the framework of NEMA, 1998, the protection of species and ecosystems that warrant national protection, the sustainable use of indigenous biological resources and the fair and equitable sharing of benefits arising from bioprospecting of genetic material derived from indigenous biological resources. http://www.info.gov.za/acts/2004/a10-04/a10-04a.pdf	DEA and provincial environment and conservation departments

POLICY/LAW/BILL/ REGULATION	CONTENT and WEBLINK	RESPONSIBLE INSTITUTIONS
NEM: Protected Areas Act (No. 57 of 2003)	Provides for the declaration and management of protected areas, and promotes sustainable utilization of protected areas for the benefit of people, as long as the ecological character of the area is preserved. http://www.info.gov.za/view/DownloadFileAction?id=68034	DEA
National Environmental Laws Amendment Act (No. 14 of 2009)	The Act, *inter alia*, amends the Biodiversity Act, so as to introduce notification requirements in the discovery phase of a bioprospecting project, take into consideration knowledge of specific individuals when issuing specific bioprospecting permits, allow the Director-General or a trustee to manage the Bioprospecting Fund, and allow for the renewal or amendment of a permit. http://us-cdn.creamermedia.co.za/assets/articles/attachments/21918_act14_2009.pdf	DEA
National Forests Act (No. 84 of 1998)	Overall purposes include the sustainable use, management and development of forests, the restructuring of State forestry, the protection of certain forests and trees, the promotion of community forestry and enhanced participation. Certain activities may be licensed in State forests, including the collection of biological resources. http://www.info.gov.za/view/DownloadFileAction?id=70742	DAFF, National Forests Advisory Council, National Forest Recreation and Access Trust, provincial departments
National Heritage Resource Act (No. 25 of 1999)	Aims to promote good management of the national estate, and to enable and encourage communities to nurture and conserve their legacy so that it may be bequeathed to future generations. Defines intangible cultural or living heritage. http://www.dac.gov.za/acts/a25-99.pdf	Department of Arts and Culture (DAC)
Traditional Health Practitioners Act (No. 35 of 2004)	To provide a regulatory framework to ensure the efficacy, safety and quality of traditional health care services. http://www.info.gov.za/view/DownloadFileAction?id=67974	DOH
World Heritage Convention Act (No. 49 of 1999)	Recognises that cultural and natural heritage are priceless and irreplaceable possessions of South Africa, and acknowledges that their loss, through deterioration, disappearance or damage through inappropriate development, constitutes an impoverishment of the heritage of all South Africans. http://www.polity.org.za/article/world-heritage-convention-act-no-49-of-1999-1999-01-01	DEA
BILLS		
Intellectual Property Laws Amendment Bill (2010)	The proposed amendments seek to give effect to the Government's policy to recognise and afford protection to indigenous knowledge as a national heritage and asset, and to ensure that indigenous communities benefit from such recognition and protection. http://us-cdn.creamermedia.co.za/assets/articles/attachments/27226_100422b8-10.pdf	DTI

POLICY/LAW/BILL/ REGULATION	CONTENT and WEBLINK	RESPONSIBLE INSTITUTIONS
REGULATIONS		
NEM Biodiversity Act: Regulations on Bio-prospecting, Access and Benefit Sharing (No. R 138 of 2008)	Regulates bioprospecting in South Africa. National Minister for Environmental Affairs is responsible for issuing bioprospecting and export permits for bioprospecting purposes. Foreigners may only apply for permits jointly with a South African collaborator. Export must be in the public interest. A benefit-sharing agreement may be refused if there is no provision for enhancing scientific and technical capacity to conserve, use and develop biodiversity or to promote conservation. http://us-cdn.creamermedia.co.za/assets/articles/attachments/11981_regulation138_of_2008.pdf	DEA
NEM Biodiversity Act: Convention on International Trade in Endangered Species Regulations (No. R 173 of 2010)	Regulates the import, export and re-export of threatened or protected species listed under the Schedule of the CITES Regulations. http://www.environment.gov.za/sites/default/files/legislations/nemba_wildfaunaandflora_g33002rg9240gon173.pdf	DEA and provincial departments
NEM Biodiversity Act: Regulations on Threatened or Protected Species (No. R 152 of 2007)	Aim to further regulate the permit system set out in Chapter 7 of the Biodiversity Act as it applies to restricted activities involving specimens of listed threatened or protected species; it provides for the prohibition of specific restricted activities involving specific listed threatened or protected species; and provides for the protection of wild populations of listed threatened species. http://www.environment.gov.za/sites/default/files/legislations/nemba_threatenedspecies_regulations_g29657rg8638gon152.pdf	DEA and provincial departments
PROVINCIAL LEGISLATION		
Various provincial ordinances and Acts	Twenty-eight legal instruments for nature conservation exist at the provincial level. In general they allow for the establishment and protection of nature reserves, for the conservation of threatened species, and for fishing and hunting. Many of these laws are outdated and the nine provinces are at different stages of phasing out old laws and developing and implementing new ones. Additionally, these instruments place restrictions on collecting, harvesting and picking indigenous biological resources and prescribe the permitting arrangements for research purposes.	Provincial environmental and conservation departments

Appendix 6: Useful websites and contacts

USEFUL WEBSITES: INTERNATIONAL ORGANISATIONS		
ORGANISATION	**DESCRIPTION**	**WEBLINK**
CBD Convention on Biological Diversity	The website of the international treaty provides information on the treaty and its programmes with sections of interest to local and indigenous communities, civil society, business and local authorities. For example, the website contains an information kit on ABS which includes factsheets on uses of genetic resources, traditional knowledge, the Bonn Guidelines and national implementation.	http://www.cbd.int
FAO-ITPGRFA Food and Agriculture Organization – International Treaty on Plant Genetic Resources for Food and Agriculture	A global treaty adopted in 2004 which aims at: • recognising the enormous contribution of farmers to the diversity of crops that feed the world; • establishing a global system to provide farmers, plant breeders and scientists with access to plant genetic materials; and • ensuring that recipients share benefits they derive from the use of these genetic materials with the countries where they originated.	http://www.planttreaty.org/
ICTSD International Centre for Trade and Sustainable Development	An independent, non-profit, and non-governmental organization which was founded in Geneva in September 1996. ICTSD aims to influence the international trade system such that it advances the goal of sustainable development. The organisation engages a broad range of actors in ongoing dialogue on trade and sustainable development policy.	http://ictsd.org/
ISE International Society for Ethnobiology	The ISE actively promotes and supports the inextricable linkages between biological and cultural diversity and the vital role of indigenous and local peoples in stewardship of biological diversity and cultural heritage. The ISE publishes a code of ethics that provides a framework for decision-making and conduct for ethnobiological research and related activities.	http://www.ethnobiology.net/ http://www.ethnobiology.net/ethics.php
UEBT Union for Ethical Biotrade	The UEBT is a non-profit association that promotes the "sourcing with respect" of ingredients that come from native biodiversity. Members commit to gradually ensuring that their sourcing practices promote the conservation of biodiversity, respect traditional knowledge and assure the equitable sharing of benefits all along the supply chain.	http://www.ethicalbiotrade.org/
WIPO World Intellectual Property Organization	WIPO is a specialised agency of the United Nations, established in 1967, dedicated to developing a balanced and accessible international intellectual property system, which rewards creativity, stimulates innovation and contributes to economic development while safeguarding the public interest.	http://www.wipo.int/

USEFUL GOVERNMENT CONTACTS: NATIONAL DEPARTMENTS		
STATE DEPARTMENT/ PUBLIC ENTITY	**CONTACT PERSON**	**WEBLINK/EMAIL**
NATIONAL DEPARTMENTS		
Department of Environmental Affairs	Director-General Private Bag X 447, Pretoria, 0001 **General Tel:** 086 111 2468/ 012 310 3911	http://www.environment.gov.za **E-mail:** callcentre@environment.gov.za
Department of Agriculture, Forestry and Fisheries	Director-General Private Bag X 250, Pretoria, 0001 **General Tel:** 012 319 6000	http://www.daff.gov.za
Department of Science and Technology **Indigenous Knowledge Systems Office (NIKSO)**	Director-General Private Bag X 894, Pretoria, 0001 **Tel:** 012 843 6816 **General Tel:** 012 843 6300 National Indigenous Knowledge Systems Office, Department of Science and Technology **Tel: 012 843 6551**	http://www.dst.gov.za
Department of Trade and Industry	Director-General Private Bag X 84, Pretoria, 0001 **Tel:** 012 394 1564 **General Tel:** 0861 843 384	http://www.dti.gov.za
Department of Health	Director-General Private Bag X 828, Pretoria, 0001 **Tel:** 012 395 9165 **General Tel:** 012 395 8000/ 9000	http://www.doh.gov.za
PROVINCIAL DEPARTMENTS		
Eastern Cape Department of Economic Development and Environmental Affairs	Head of Department Private Bag X 0054, Bhisho, 5605 **Tel:** 043 605 8000	http://www.dedea.gov.za/
Free State Department of Economic Development, Tourism and Environmental Affairs	Head of Department Private Bag X 20801, Bloemfontein, 9300 **Tel:** 051 400 4731 **Tel:** 051 404 9600	www.detea.fs.gov.za
Gauteng Department of Agriculture and Environmental Affairs	Head of Department P O Box 8769, Johannesburg, 2000 **General Tel:** 011 355 1900	http://www.gdard.gpg.gov.za/
Limpopo Department of Economic Development, Environment and Tourism	Head of Department Private Bag X 9484, Polokwane, 0700 **Tel:** 015 293 8564 **General Tel:** 015 293 8300	http://www.ledet.gov.za/ **E-mail:** info@ledet.gov.za
Mpumalanga Department of Economic Development, Environment and Tourism	Head of Department Private Bag X 11215, Nelspruit, 1200 **Tel:** 013 766 4179 **General Tel:** 013 766 4004	http://www.mpumalanga.gov.za/dedet/
Northern Cape Department of Environment and Nature Conservation	Head of Department Private Bag X 6120, Kimberley, 8301 **Tel:** 053 807 7306 **General Tel:** 053 807 7300	http://denc.ncpg.gov.za/
North West Department of Economic Development, Environment, Conservation and Tourism	Head of Department Private Bag X 2039, Mmabatho, 2735 **Tel:** 018 389 5146/5104 **General Tel:** 018 389 5111	http://www.nwpg.gov.za

USEFUL GOVERNMENT CONTACTS: NATIONAL DEPARTMENTS		
STATE DEPARTMENT/ PUBLIC ENTITY	**CONTACT PERSON**	**WEBLINK/EMAIL**
PUBLIC ENTITIES		
KwaZulu-Natal Ezemvelo KZN Wildlife	Chief Executive Officer P O Box 13053, Cascades, 3202 **General Tel:** 033 845 1000	http://www.kznwildlife.com/
Western Cape CapeNature	Chief Executive Officer Private Bag X 29, Gatesville, 7766 **General Tel:** 021 483 0000	http://www.capenature.org.za/
South African National Parks	Chief Executive Officer P O Box 787, Pretoria, 0001 **General Tel:** 012 426 5000	http://www.sanparks.org.za
South African National Biodiversity Institute	Chief Executive Officer Private Bag X 101, Pretoria, 0001 **General Tel:** 012 843 5000	http://www.sanbi.org.za **E-mail:** info@sanbi.org.za


ISBN 978-0-621-40885-0