



environmental affairs

Department:
Environmental Affairs
REPUBLIC OF SOUTH AFRICA

***Brief guide to completing a
bioprospecting permit
application***

PRESENTATION CONTENTS

- Permit application checklist
 - Make sure you have attached all required information and documents
- Application procedure
 - Brief explanation of the application procedure
- What does the legislation say?
 - Legislative overview
- Pre-application information checklist
 - Questions to ask yourself before starting to complete the permit application forms
- Bioprospecting permits
 - The evaluation process, permit contents, conditions and permit holder duties
- Contact details



PERMIT APPLICATION CHECKLIST

Please ensure that you have completed and attached the following:

1. Annexure 2:

- a. Part 1 for a bioprospecting permit; *OR*
- b. Parts 1 & 2 for an integrated export and bioprospecting permit

1a	
1b	

2. Annexure 7: Material transfer agreement(s)

2	
3	
4	

3. Annexure 8: Benefit sharing agreement(s)

4. Project proposal

5. Proof of steps taken to identify:

- a. Traditional knowledge associated with the indigenous biological resource; and
- b. The traditional knowledge holders

5a	
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5b	
6	

6. Certified copies of identity documents of applicants



APPLICATION PROCEDURE

- Complete and submit bioprospecting permit application with associated material transfer and benefit sharing agreements
- Receive acknowledgment letter of receipt of application and supporting documentation, and application reference number
- Pay permit application fee using application reference number
- Complete permit application forwarded to the Bioprospecting Advisory Committee for review
- Receive feedback from the Bioprospecting Advisory Committee (e.g. request for more information)
- Recommendation from the Bioprospecting Advisory Committee forwarded to the Minister for consideration
- Minister approves the BSA and MTA and issuing of the permit
- Permit issued and signed by the Director-General
- Permit sent by registered mail to applicant



WHAT DOES THE LEGISLATION SAY?

National Environmental Management Biodiversity Act, 2004 (Act 10 of 2004) (NEMBA)

NEMBA Chapter 6: Section 81(1)

81(1) A person may **not without a permit**

- engage in the **commercialisation** phase of bioprospecting involving IBR, or
- **export** IBR for bioprospecting or any other kind of research

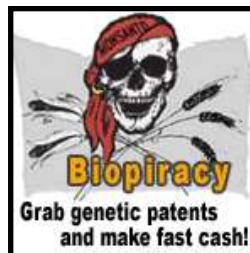


BIOPROSPECTING, ACCESS & BENEFIT SHARING REGULATIONS

- **Bioprospecting, Access and Benefit Sharing (BABS) Regulations, 2008**
- Regulates the bioprospecting permit system
- Applies to:
 - discovery & commercialisation phases
 - export of any IBR from South Africa for bioprospecting, or any other kind of research
- Set out the contents, requirements & criteria for benefit-sharing & material transfer agreements
- Came into force on 1 April 2008
- Annexure 2: Permit application form
- Annexure 7: Material Transfer Agreement (MTA)
- Annexure 8: Benefit Sharing Agreement (BSA)

PRE-APPLICATION INFORMATION CHECKLIST

1. What is being used?
2. Is it indigenous?
3. Where does it come from and where is it going?
4. What is being done with it?
5. Is there traditional knowledge associated with it?



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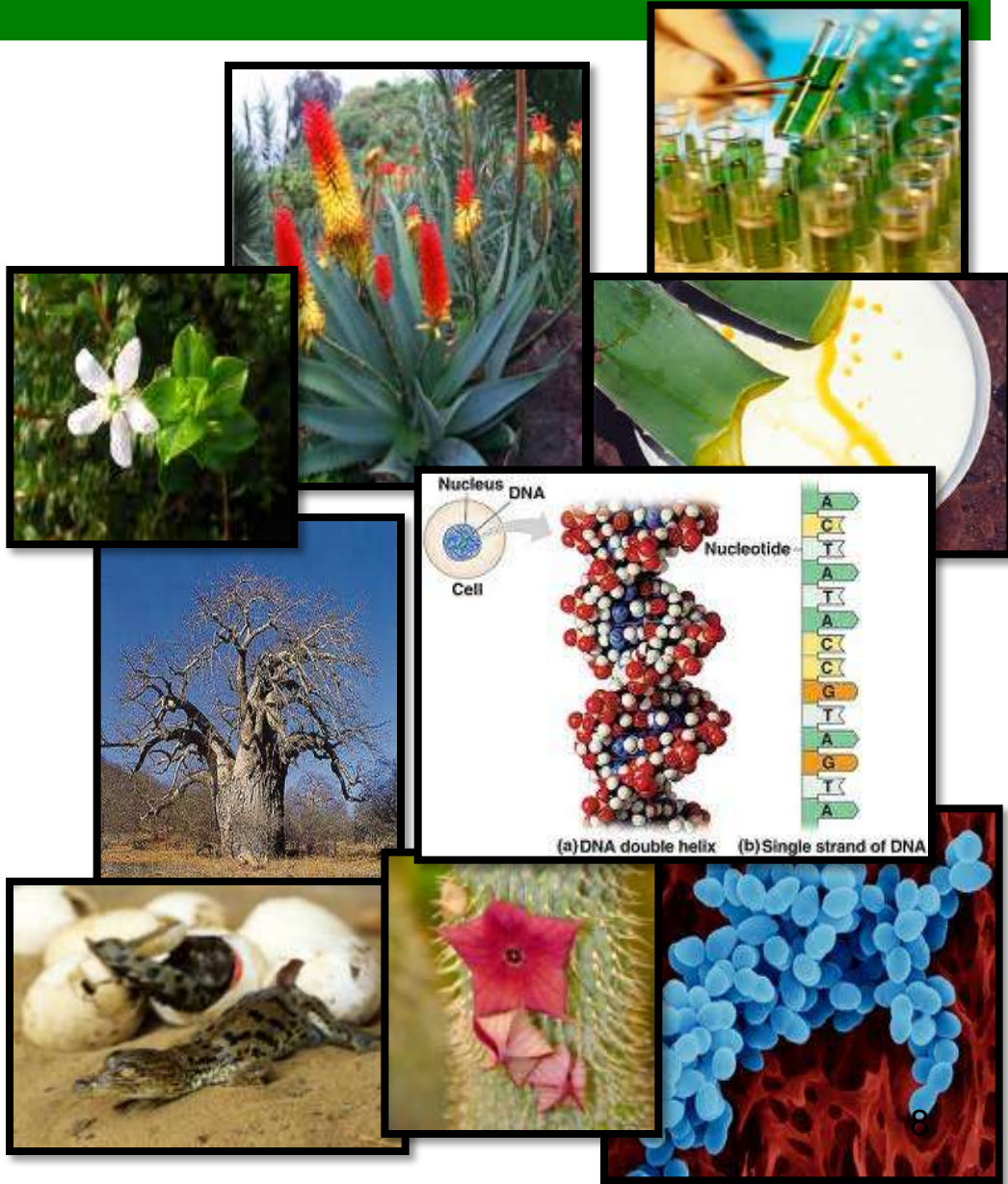
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WHAT IS BEING USED?

- Plant
- Animal
- Any other organism

- Derivative = part, tissue, extract, chemical compound

- Genetic material = contains functional units of heredity



IS IT INDIGENOUS?

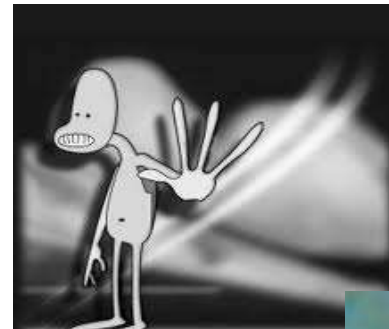
Indigenous species

- Indigenous \neq endemic
- Occurs or historically occurred in nature in RSA
- Excludes species introduced through human activity



Exotic / alien species

- Not subject to national legislation
- Must provide evidence of origin of material



INDIGENOUS BIOLOGICAL RESOURCES

Animals, plants or other organisms of indigenous species

Includes

- Living or dead
- Genetic material
- Gathered from the wild
- Cultivated, bred or kept in captivity
- **Exotic** animals, plants or other organisms altered with genetic materials or bio-compounds from indigenous species



Excludes

- Genetic material of human origin
- All other exotic animals, plants or other organisms



"Man's heart away from nature becomes hard."



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INFOBASES

Overview

Infobases

SANBI in collaboration with partners, have developed a range of websites, databases and other electronic resources to provide biodiversity information. Some are more technical and others are designed with the general public in mind. These online resources include:



[Biodiversity Advisor](#): The Biodiversity Advisor helps you use SANBI's online biodiversity information resources for making, planning and research.



[SIBIS](#) (SANBI's Integrated Biodiversity Information System) which provides threatened species information, distribution area checklists and general species details.



[POSA](#) (Plants of Southern Africa) A site which provides information about all SA plants, their distribution and current status.

WHERE DOES IT COME FROM?

Material transfer agreement required

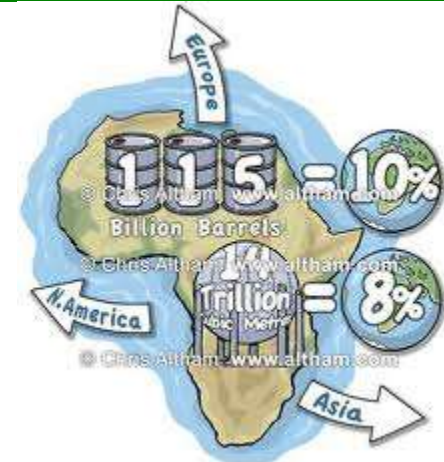
- Supplier
- Community
- Land owner

No material transfer agreement required

- Own land or cultivation

WHERE IS IT GOING TO?

- South African market
- International market



WHAT IS BEING DONE WITH IT?

Commercialisation phase

- Nature and extent of actual or potential commercial exploitation is sufficiently established to begin process of commercialisation

Commercialisation

- Patent application or Intellectual Property rights
- Clinical trials and product development
- Multiplication through cultivation, propagation, cloning or other means (synthesizing) to develop and produce: drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours and extracts

IS THERE ASSOCIATED TRADITIONAL KNOWLEDGE?

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SCIENTIFIC FACTS

Three decades ago, South African scientists at a government lab

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Imuvitox Spray
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cancer bush 50ml.
R120.00



Infection Spray 50ml.
R120.00



Bloodstream Spray
50ml.



SA HealthInfo

Traditional medicines database



Gain entry into the Traditional medicines database by selecting any entry point below

Plant

Treatments

Toxicology



Pharmacology

Chemistry



UWC

Contact details:

South African Traditional Medicines Research Unit, Dept. of Pharmacology, Faculty of Health Sciences, University of Cape Town, 7925 Observatory, South Africa
email : satmerg@uctgsh1.uct.ac.za



UCT

Information from the Noristan, Pharmel and Watt & Breyer-Brandwijk databases also available.

TRAMEDIII (South African Traditional Medicines Database)

Disclaimer:

The traditional medicines database was developed by the South African Traditional Medicines Research Unit, Dept. of Pharmacology, Faculty of Health Sciences, University of Cape Town and is for personal use only. The data may not be used for commercial purposes and it does not replace the advice of a trained professional. Every attempt has been made by the MRC to ensure that all information provided is correct and accurate. All rights are reserved.
SAHealthInfo



HOW DO I APPLY FOR A BIOPROSPECTING PERMIT?

- Source documents www.environment.gov.za
- Use [Annexure 2](#) of the BABS Regulations
- Ensure that sufficient information is provided in the application to enable the Minister to make an assessment
- Attach the signed Benefit Sharing Agreement(s) and Material Transfer Agreement(s)
- Pay the non-refundable permit application fee
 - Bioprospecting permit: R 5 000 **OR**
 - Integrated export and bioprospecting permit R 5 200
- Contact DEA officials for assistance





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For office use only
Reference number here

- PART 1: APPLICATION FOR A BIOPROSPECTING PERMIT**
- PART 2: APPLICATION FOR AN EXPORT PERMIT FOR THE PURPOSES OF BIOPROSPECTING**

Notes on completing form:

1. If you are applying for a bioprospecting permit and you do not intend to export the relevant indigenous biological resources, you need only to complete part 1 of this form.
2. If you are applying for an integrated export and bioprospecting permit, you must complete parts 1 and 2 of this form.
3. If insufficient space is provided in this form, additional information may be included by way of Annexures.

KIND OF PERMIT APPLIED FOR (Tick relevant box)

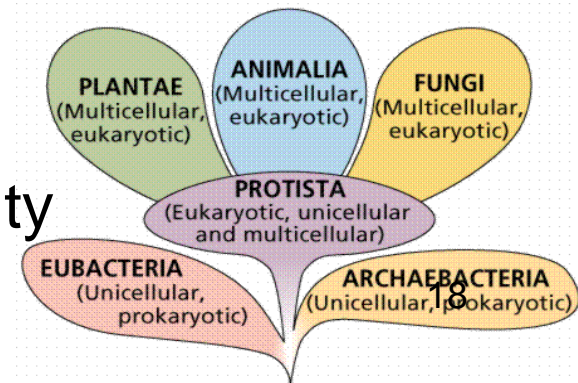
- Bioprospecting permit:**
- Integrated export and bioprospecting permit:**

PHASE OF BIOPROSPECTING PROJECT (Tick relevant box)

- Discovery phase:**
- Commercialisation phase:**

ANNEX 2 PERMIT APPLICATION

- **Part 1: Bioprospecting permit**
- **Part 2: Export permit**
- Q1 – 7: Juristic persons
- Q8 – 12: Natural persons
- Q13 – 37: All applicants
- Q13 Other Collaborators: Researcher, product developer, part of consortium
- Q15 Project leader: Researcher / Manager / Owner
- Q19 National sponsors: e.g. DST, DTI, ECDC, ARC, MRC,
- Q 21 Indigenous Biological Resource:
 - Type: Plant / animal / other organism
 - Family / genus & species: common and / or scientific name
 - Quantity: amount required
 - Locality data: supplier / farm / community



ANNEX 2 PERMIT APPLICATION ...2

- Q22 Other permits: CITES, TOPS or Provincial harvesting permit; Phytosanitation
- Q26 Disclosure of information: Does the provider of the resource know (broadly) what you intend to do with the resource?
- Q28 Access provider: where you obtain the resource from
- Q29 Traditional Knowledge: Public notice, literature search
- Q30 TK: As disclosed by the community / recorded in literature
- Q31 TK BSA: Indigenous community who owns the knowledge
- Q34 Intervention: If there is not agreement between parties on the BSA



ANNEX 2 PERMIT APPLICATION ...3

- Q36 Project proposal
 - Objectives
 - Benefits
 - Methodology
 - Time-frames
 - Environmental considerations
 - Reporting: annual or bi-annual
 - Outcomes
 - Discarded specimens
- Q37 Application fee: R 5 000,00 – pay after submission of application and receipt of reference number
- Sign application
- Attach supporting documents:
 - Certified copies of identity documents
 - Copies of other permits / authorizations
 - Signed material transfer and benefit sharing agreements



ANNEX 2 PERMIT APPLICATION ...4

- **Part 2: Export permit**
- Q1 Importer: who will receive this material
- Q3 Other legislation: DAFF Phyto-sanitation, CITES, ToPS, SARS, DTI
- Q4 Purpose of export: what is the material going to be used for?
- Q7 Application fee: R 5 200,00 – pay after submission of application and receipt of reference number



ANNEX 7 MATERIAL TRANSFER AGREEMENTS

- [Material Transfer Agreement](#) (MTA) regulates access to the resource
 - includes purchase of raw / processed material for further development and application

MTA must specify –

- Particulars of the material provider, exporter and recipient
- The type, area or source, & quantity of IBR
- The purpose for which such IBR are to be exported
- The potential uses of the IBR
- Conditions under which the recipient may provide any such IBR or their progeny, to a third party
- MTA must be **approved** by the Minister to take effect



COMPLETING THE MTA

- Q1 Juristic recipient: company that purchases material
- Q2 Natural recipient: person who purchases material
- Q3 Access provider: supplier of material – natural or juristic
- Q4 IBR: what material is obtained from the access provider
- Q5 Current use: what is the current use by the access provider of the material
- Q6 Purpose of export: why the material must be sent away
- Q7 Third parties: when the material may be made available to 3rd party
- Sign material transfer agreement
- Submit for approval by the Minister of Water & Environmental Affairs



ANNEX 8 BENEFIT SHARING AGREEMENTS

- [Benefit Sharing Agreements](#) regulates monetary & non-monetary benefits due to access providers and traditional knowledge holders

BSA must specify –

- Names of the parties to the BSA
- Type, area or source, quantity, any traditional uses, present / potential uses of IBR
- Set out the details of the IBR utilization / exploitation
- Set out the details of sharing of benefit with stakeholders of any benefits that may arise from bioprospecting
- Provide for a regular review of the agreement
- BSA must be submitted to the Minister for **approval** to take effect



COMPLETING THE BSA

- Q1 Juristic permit applicant
- Q2 Natural applicant
- Q3 Access provider: supplier of material – natural or juristic
- Q4 Indigenous community: community that owns the traditional knowledge used in the bioprospecting project
- Q5 IBR: what material is obtained from the access provider
- Q6 Current use: what is the current use by the access provider of the material
- Q7 Intended use: objective of the bioprospecting project
- Q8 TK: Recorded traditional use of the IBR



COMPLETING THE BSA ...2

- Q9 Benefit sharing: monetary and non-monetary
 - Benefits for access to the resource
 - Benefits for use of the TK
 - Provide details
- Examples of benefit sharing:
 - Purchase of material = upfront payments
 - Research exchange and collaboration
 - Provision of equipment, infrastructure support and technologies
 - Royalty payments
 - Preferential access to developed product
 - Joint IP ownership
 - Training of scientists / technicians / researchers
- Q11 BSA review: regular period as agreed, based on stage of project
- Sign benefit sharing agreement
- Submit for approval



PERMIT EVALUATION PROCEDURE

- Acknowledgement of receipt of application and documentation – receive reference number BABS/000000**P**
- If documentation complete and consistent (annex 2, 7, 8) then forwarded to Bioprospecting Expert Group
- Bioprospecting Expert Group = advisory committee appointed by the Minister from Provincial authorities, DST, DTI , DAFF, DoH, SANBI, SANParks
- Convene quarterly or when there are 4 permit applications
- Evaluate BSA and permit applications
- Make recommendation to Minister for consideration
- Minister approves agreements and issue permit



BIOPROSPECTING PERMIT

A permit may only be issued if

- Rights of stakeholders are protected
- MTA approved
- BSA approved
- Bioprospecting contribute to
 - Conservation of biodiversity
 - Economic development; or
 - Enhancing scientific knowledge and technical capacity



BIOPROSPECTING PERMIT CONTENTS

The bioprospecting [permit](#) specifies –

- Particulars of the permit holder/s
- Period of validity
- IBRs involved
- Quantity of IBRs involved
- Source of the IBRs
- Agreements entered into
- [Permit conditions](#)



GENERIC PERMIT CONDITIONS

- Money due to stakeholders must be paid into the Bioprospecting Trust Fund
- Permit holder must submit status reports annually / bi-annually
- Permit holder is liable for costs of mitigating or remedying the impact of the bioprospecting project on the environment
- The IBRs to which a permit relates may not be sold, donated or transferred to a 3rd party without the written consent of the Minister



DUTIES OF PERMIT HOLDERS

The permit holder must –

- Submit a status report to the issuing authority on annual basis or on timeframes as determined by the issuing authority
- Notify the DEA DG when money due to stakeholders as specified in the BSA will be transferred into the Bioprospecting Trust Fund
- Notify stakeholders entitled to a monetary benefit in terms of a BSA that money was transferred into the Bioprospecting Trust Fund
- Mitigate or remedy any impact on the IBR



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Environmental Crime Hotline 0 800 205 005



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