BIOPROSPECTING POLICY AND LEGISLATION

CTFA

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Biodiversity and Conservation

environmental affairs

Department:
Environmental Affairs
REPUBLIC OF SOUTH AFRICA

PRESENTATION OUTLINE

- Overview
- NEMBA
- BABS Regulations
- Implementation

OVERVIEW: SOUTH AFRICAN BIODIVERSITY

- 3rd most biologically diverse country in the world, after Indonesia & Brazil.
- 2 oceans: the Atlantic and Indian.
- Occupies about 2% of the world's land area, but is home to nearly 10% of the world’s plant; 7% of reptiles, birds & mammals; 15% of known coastal marine species.







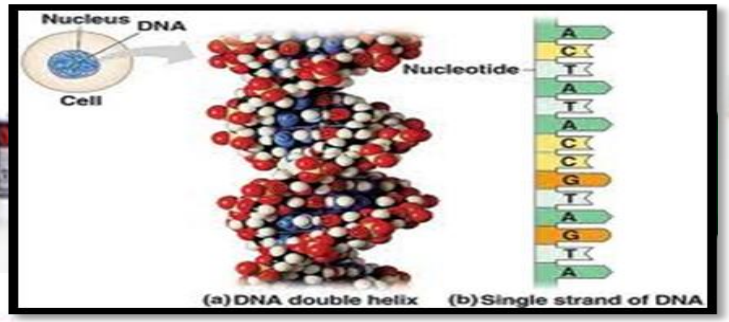


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OVERVIEW: SOUTH AFRICAN BIODIVERSITY

- One of South Africa's greatest assets.
- Rich in indigenous biological resources (IBRs) and cultural diversity.
- Rich with traditional knowledge (TK) on properties of plants, seeds, algae & other IBRs.
- IBRs & TK desired by academics & commercial scientists to develop new information / commercial products.



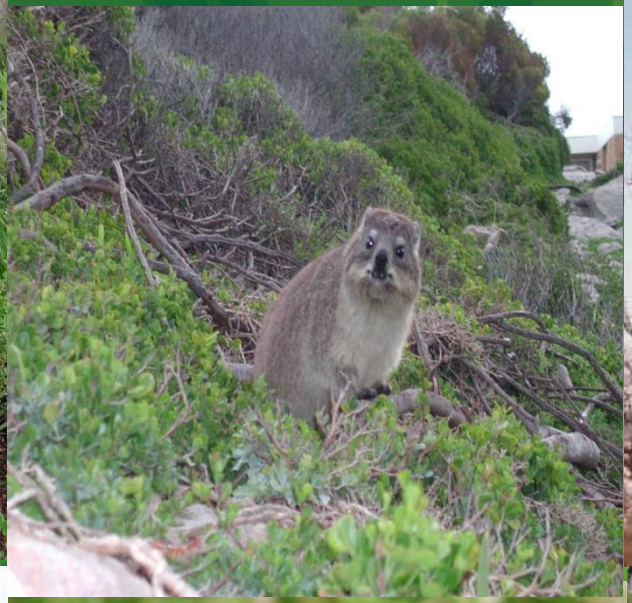




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SA'S INDIGENOUS BIOLOGICAL RESOURCES













IMPORTANCE OF INDIGENOUS BIOLOGICAL RESOURCES AND ASSOCIATED TRADITIONAL/ INDIGENOUS KNOWLEDGE











OVERVIEW: BIOPROSPECTING IN SOUTH AFRICA

- Historically, bioprospecting was free for all
- This unregulated bioprospecting led to biopiracy with –
  - Unfair, inequitable and no sharing of benefits arising from bioprospecting;
  - Unsustainable use of indigenous biological resources (IBRs);
- These concerns led to the development of International and National legislation and frameworks.

OVERVIEW: OVERALL POLICY OBJECTIVES

To redress the injustice of the past in order to achieve socio-economic development goals ~ fair & equitable benefits sharing.

To provide regulatory framework for bioprospecting / biotrade activities ~ attain conservation and sustainable utilization of indigenous biological/genetic resources ~ Permitting System.

To provide obligatory requirements to the regulated sectors to recognize existing traditional knowledge on the usefulness of indigenous biological/genetic resources ~ Benefit Sharing Agreements.

To provide obligatory requirements to the regulated sectors to seek permission from the land owners to access/collect indigenous biological/ genetic resources ~ Material Transfer Agreements and Benefit Sharing Agreements.

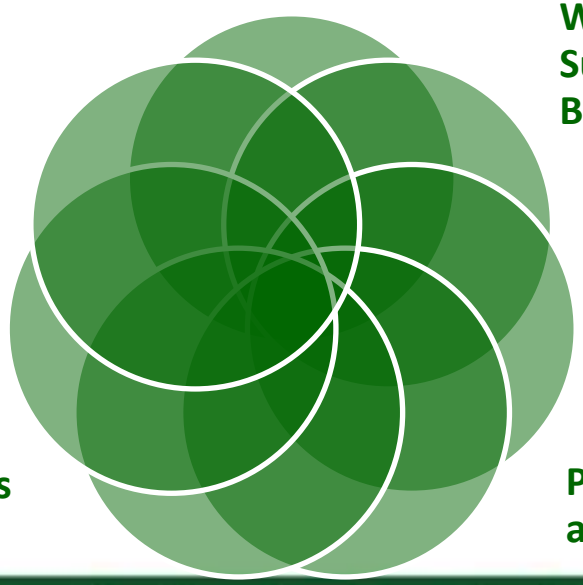
To implement international regulatory obligations adopted by South Africa

RELEVANT LEGISLATIVE FRAMEWORKS IN SOUTH AFRICA

CBD & Nagoya Protocol on Access to Genetic Resources & the Fair and Equitable Sharing of Benefits Arising from their Utilisation

Constitutional mandate & NEMA

White Paper on Conservation & Sustainable Use of South Africa's Biodiversity of 2007



Constitutional Concurrent Mandate, Provincial Ordinance

NEMBA, BABS Regulations, TOPS Regulations & CITES Regulations

Indigenous Knowledge Systems Policy-administered by DST

Patent Amendment Act-administered by DTI

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KEY TERMS

Bioprospecting means any research on, development or application of indigenous genetic/biological resources (IGBRs) for commercial exploitation & includes-

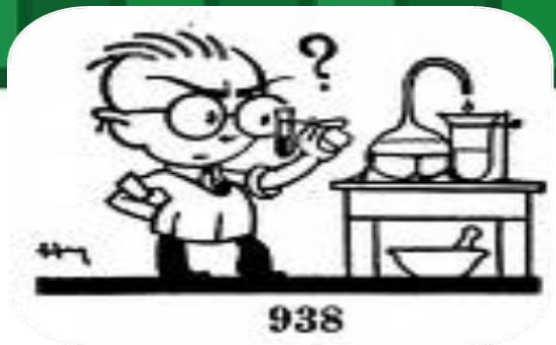
a) *the systematic search, collection or gathering of IGBRs or making extractions from IGBRs; or*

b) *the utilisation of any information regarding any traditional uses of IGBRs by indigenous communities; or*

c) *research on, or the application, development or modification of traditional uses of IGBRs for commercial exploitation; or*

d) *trading in & exporting of IGBRs in order to develop and produce products such as industrial enzymes, fragrances, cosmetics, extracts, essential oil, drugs; medicines, food flavours & colours.*







KEY TERMS CONT…

NEMBA categorized bioprospecting into 2 phases:

1. Discovery phase

means any research on IGBRs where the nature & extent of any actual or potential commercial exploitation in relation to the project is not sufficiently clear or known to begin the process of commercialisation.

2. Commercialisation phase

means any research on, or development or application of IGBRs where the nature & extent of any actual or potential commercial exploitation in relation to the project is sufficiently established to begin the process of commercialisation.

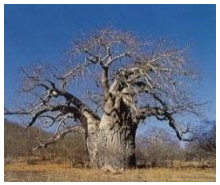
KEY TERMS CONT….

IGBRs -animals, plants or microorganisms of indigenous species

Includes

- Living or dead
- Genetic material gathered from the wild , cultivated, bred or kept in captivity

- **Exotic** species altered with genetic materials or bio-chemical compounds from indigenous species







Excludes

- Genetic material of human origin
- All other exotic species

KEY TERMS CONT….

Commercialisation includes the following activities-

- *Filing of complete intellectual property (IP) / patent application in SA or elsewhere;*
- *Obtaining or transfer of IP rights;*
- *Commencement of product development, including conducting market research & seeking pre-market approval for the sale of resulting products;*
- *Multiplication of IGBRs through cultivation, propagation, or cloning to develop & produce products such as: drugs, medicines, industrial enzymes, food flavours, fragrances, cosmetics, essential oils, emulsifiers, oleoresins, colours & extracts.*

KEY TERMS CONT….

- **Biotrade** means the buying & selling of milled, powdered, dried, sliced or extract of IGBRs for further commercial exploitation.

- **Commercial exploitation** means engaging in any bioprospecting activity with the intention of making a profit.

- **Traditional use or knowledge** refers to the customary utilisation or knowledge of IGBRs by indigenous community or specific individual, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted & recognised by them, & include discoveries about the relevant IGBR by that community or individual.

KEY TERMS CONT….

- **Material Transfer Agreement** refers to an agreement between the applicant & any person or organ of state or community providing access to IGBRs to which the application relates.

- **Benefit Sharing Agreement** refers to an agreement that provides for sharing of any future benefits that may be derived from bioprospecting between:
  - *the applicant & any person or organ of state or community providing access to IGBRs to which the application relates; and/or*
  - *the applicant & an indigenous community or specific individual whose traditional uses/knowledge/discoveries on IGBRs to which the application relates have initiated or are to be used in the proposed bioprospecting.*

KEY TERMS CONT….

- **Confidential Information** refers to information which, if disclosed, may be detrimental to the commercial, associated traditional knowledge or financial interests of the a party involved, and includes:

- *Information about research being or to be carried out including details of species to be collected and areas in which specified species are to be collected;*
- *Financial, commercial, scientific or technical information including trade secrets;*
- *Traditional knowledge if the disclosure of that knowledge may be detrimental to the relevant indigenous community or specific individual*

But excludes:

- *Information that has already been disclosed through publication in a scientific journal;*
- *Information that parties consent to its disclosure.*

NATIONAL BIODIVERSITY ACT

- Provide within the NEMA framework for, amongst other:
- ➢ Management and conservation of biological diversity within South Africa;
- ➢ Use of indigenous biological resources in a sustainable manner;
- ➢ Fair and equitable sharing of benefits arising from the use of indigenous biological resources and associated traditional/indigenous knowledge;

KEY PROVISIONS: NEMBA CHAPTER 6 REQUIREMENTS

- Chapter 6 of NEMBA provides a framework for:

➢ The regulation of bioprospecting involving indigenous biological resources

➢ The regulation of export from the Republic of indigenous biological resources for purposes of bioprospecting

➢ a fair and equitable sharing of benefits arising from bioprospecting involving commercial utilization of indigenous and biological resources and associated traditional knowledge

➢ to ensure that the nation's indigenous biological resources are developed and utilized in an ecologically sustainable manner while promoting social and economic development, in particular in the areas where the indigenous biological resources and associated traditional knowledge is accessed

KEY PROVISIONS: NEMBA CHAPTER 6 REQUIREMENTS

- Permit requirements (Section 81)
- Notification requirements (Section 81A)
- Protection of interests of Access Providers and/or Traditional/Indigenous Knowledge Holders (Section 82)
- Bioprospecting Trust Fund (Section 85)
- Exemptions (Section 86)

KEY PROVISIONS:NEMBA CHAPTER 6 & INDIGENOUS COMMUNITIES

Chapter 6 of NEMBA calls for the protection of certain interest of the following stakeholders before a permit is issued:

- A person, including organ of states, or community providing or giving access to the indigenous biological resources to which the permit application relates

- An indigenous community whose traditional use or discoveries of the indigenous biological resources to which the permit application relates have initiated or will contribute to the proposed bioprospecting/ biotrade

KEY PROVISIONS: NEMBA CHAPTER 6 ENABLING PROVISIONS

NEMBA requires the permit applicants to fulfil the following requirements to ensure protection of the rights of the indigenous communities:

- Must disclose all material/important information about the bioprospecting/ biotrade project to the identified access provider/ TK holders.
- Must obtain prior consent for access to IBR & / or use of TK.
- Must enter into material transfer agreements (MTA).
- Must enter into benefit sharing agreements (BSA).
- BSA & MTA must be approved by the Minister before a permit is issued.

➢ **Benefits may be Monetary or Non-monetary, e.g:**

Community development projects, Equipment and infrastructures, Royalties, Milestones payments, Upfront payments, Bursaries etc.

KEY PROVISIONS: OFFENCES

A person is guilty of an offence if that person

- Without a permit –
  - Undertakes bioprospecting/ biotrade involving IGBRs &TK
- Contravenes any provision of these Regulations
- Does not adhere to the permit conditions
- Permits, or allow any other person to do anything which is an offence in terms of these regulations

KEY PROVISIONS: PENALTIES

A person convicted of an offence is liable to –

- Fine not exceeding R5-million or imprisonment for a period not exceeding 5 years.
- Fine not exceeding R 10-million or imprisonment for a period not exceeding 10 years, in the case of second offence or subsequent conviction.
- Both fine and imprisonment

BABS AMENDMENT REGULATORY PROVISIONS

The Regs applies to:

- Commercial or industrial sectors that uses IGBRs for biotrade, or for research, application or development of drugs, complementary medicines, neutraceuticals, industry enzymes, food flavours, fragrances, cosmetics, colours, extracts & essential oils.
- …that utilises TK associated with any IGBRs.
- Non-commercial sectors that export IGBRs from the Republic for research to generate scientific data.

BABS AMENDMENT REGULATORY PROVISIONS

PERMITTING PROCESS:

1. Discovery phase

- Notification of the Minister (nationally)
- Discovery Phase Export permit (internationally)

2. Commercialisation phase

- Biotrade permit (nationally & internationally)
- Bioprospecting permit (nationally & internationally)
- Integrated biotrade & bioprospecting permit (nationally & internationally)

3. Any other kind of Research

- Export permit for research other than bioprospecting (internationally)

ISSUING AUTHORITY

Provincial Departments of Environmental Affairs (MECs)

National

Department of Environment Affairs (Minister)

Non-Commercial Research (Any other kind of Research)

Discovery phase bioprospecting

Commercialisation phase bioprospecting

Export Permit (outside RSA)

Notification (in RSA)

Discovery phase Export permit (outside RSA)

Bioprospecting Permit (in & outside RSA)

Biotrade permit (in & outside RSA)

Integrated Biotrade & Bioprospecting permit (in & outside RSA)

WHO MAY APPLY

A permit may only be applied by–

- A juristic person registered in terms of SA law.
- A natural person, who is a SA citizen or a permanent resident of SA.
- A non-juristic or natural person jointly with a juristic or natural person in terms of SA law.

PERMIT APPLICATION FEE STRUCTURE

Fees applicable to any natural person or juristic body in South Africa:

- Category I- **taxable turnover R 0-R300 000**
- Category II- **taxable turnover R300 001- R 750 000**
- Category III-**taxable turnover R 750 000 & above**
- Category IV–Bona fide research institutions

TIMEFRAMES

- The Issuing Authority:

- must consider & decide on any permit application within **120 working days** after the receipt of such an application, if satisfied that all the prescribed & requested information has been submitted.
- must within **10 working days** after the date of receipt of such an application & in writing, request the applicant to submit such information with 20 working days after date of receipt of such a request.

- If the additional information requested is not submitted to the issuing authority within **30 working days** after such a request, such an application must be deemed withdrawn.

RENEWAL & AMENDMENTS TIMEFRAMES

- Permit holder may, before the expiry, apply for renewal of such permit.

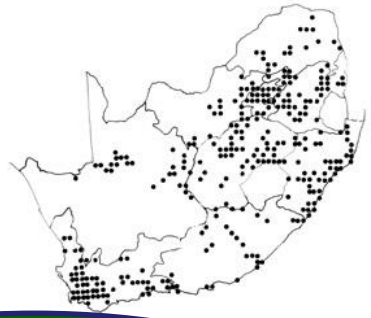
- Permit holder may, after annual project status reporting, apply for amendment of such permit.

OTHER KEY REGULATORY PROVISIONS

- How & where to submit notifications or permit applications (Chapter 3)
- Application forms (Annexes)
- Assistance by issuing authority to applicant or stakeholder (Chapter 2)
- Consultation between issuing authority & relevant stakeholders (Chapter 2)
- Issuing authority's right to access to information (Chapter 2)
- Criteria for evaluating notifications or permit applications or renewal or amendment by the issuing authority (Chapter 2 & 3)
- Circumstances for refusal of permits (Chapter 3)
- Communication of decision on notifications or permit applications by the issuing authority (Chapter 2)
- How to fulfil the BSA requirements, where relevant stakeholders cannot be identified (Chapter 4)
- How to fulfil the BSA requirements, as a Subsequent biotrader (Chapter 3)

PRACTICAL ILLUSTRATION OF REGULATIONS

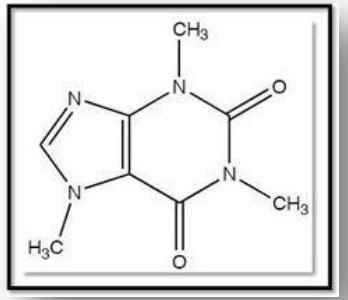
Use of traditional/indigenous knowledge



Use of indigenous biological resources



Commercial and/or Non-Commercial intent



Research on biochemical composition of resource

Extraction of biochemical compound from resource



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