

# BIOPROSPECTING, ACCESS AND BENEFIT SHARING AMENDMENT REGULATIONS

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First Bioprospecting Forum Meeting



Biodiversity and Conservation



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# PRESENTATION OUTLINE

- BABS related Legislative Framework in South Africa
- Key Terms
- NEMBA Enabling Provisions
- BABS Amendment Regulatory Provisions
- Awareness Raising & Capacity Building Materials



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# BABS RELATED LEGISLATIVE FRAMEWORK IN S.A

- **Convention on Biological Diversity**
  - *S.A became contracting Party since 1995*
- ❖ Nagoya Protocol on Access to Genetic Resources & the Fair & Equitable Sharing of Benefits Arising from their Utilisation
  - *South Africa ratified this Protocol in January 2013*
  - *Came into force in October 2014*
- **Constitution of the Republic of South Africa, 1996**
  - White Paper on Conservation & Sustainable Use of South Africa's Biodiversity of 1997
  - National Environmental Management Act, 1998 (NEMA)
  - National Environmental Management: Biodiversity Act, 2004 (NEMBA)/ NEMLA 2009/NEMLA 2013
  - **Bioprospecting, Access and Benefit Sharing Regulation of 2008/ BABS Amendment Regulations of 2015**

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# OTHER SUPPORTING LEGISLATION

- Threatened or Protected Species Regulations
- CITES Regulations
- Provincial Ordinances
- Patent Amendment Act
- IKS Policy



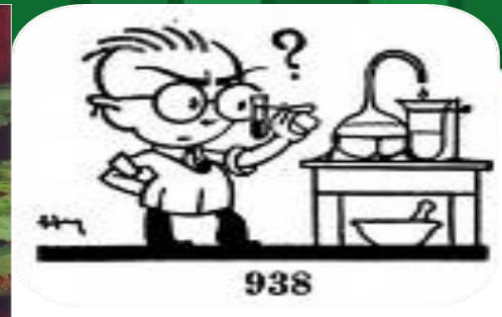
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# KEY TERMS

**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, 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.



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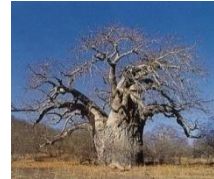
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# KEY TERMS CONT....

## 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



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# 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 IBRs 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.*



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## 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.



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# 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.*



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# NEMBA REQUIREMENTS

- Permit requirements (commercialisation phase bioprospecting or any other kind of research)
- Notification requirements (discovery phase bioprospecting)
- Stakeholder's interest protection (MTA & BSA requirements)
- Bioprospecting Trust Fund
- Exemptions
- Offences & Penalties



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# NEMBA ENABLING PROVISIONS

## Sections 81(1)

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

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

**81A:** No person may without first notifying the Minister:

- *engage in discovery phase bioprospecting involving any IGBR; and*
- *a person involved in the discovery phase of bioprospecting must sign a commitment to comply with the requirements at the commercialisation phase of bioprospecting.*



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# NEMBA ENABLING PROVISIONS

**NEMBA protects the interest of two categories of stakeholders in section 82:**

- **Access Provider**

Person / community / organ of state who provides access to IBRs.

- **Traditional Knowledge (TK) Holder**

Indigenous community or individual whose traditional uses, knowledge or discoveries of the IBRs are used as basis for bioprospecting.



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# NEMBA ENABLING PROVISIONS

**NEMBA requires the permit applicant to fulfil the following requirements:**

- Must disclose all material information about the bioprospecting project to the identified stakeholders.
- 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.



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# NEMBA ENABLING PROVISIONS

**NEMBA established the Bioprospecting Trust Fund in terms of section 85 to:**

- Receive all moneys arising from Bioprospecting projects, which are due to stakeholders from the BSA concluded between permit holder and stakeholders.
- The Director-General in DEA is responsible for the management and administration of the fund.



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# 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.



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# 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)



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# ISSUING AUTHORITY

Provincial  
Departments of  
Environmental  
Affairs (MECs)

National  
Department of Environment Affairs  
(Minister)

Non-  
Commercial  
Research (Any  
other kind of  
Research)

Export Permit  
(outside RSA)

Discovery phase  
bioprospecting

Notific  
ation  
(in  
RSA)

Discove  
ry  
phase  
Export  
permit  
(outsid  
e RSA)

Commercialisation phase  
bioprospecting

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.



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# 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**



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# 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.



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# 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.



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# OFFENCES

**A person is guilty of an offence if that person**

- Without a permit –
  - Undertakes bioprospecting involving IGBRs
- 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



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# 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



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# OTHER KEY REGULATORY PROVISIONS

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



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# TRANSITIONAL PROVISIONS

Continuation of regulated and permit issued in terms of 2008 BABS Regs:

- Pending application lodged in terms of 2008 BABS Regs would be dealt with in terms of 2015 BABS Amendment Regs.



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# AWARENESS RAISING & CAPACITY BUILDING MATERIALS

- BABS Guidelines: South Africa's Bioprospecting, Access & Benefit-Sharing Regulatory Frameworks: Guidelines for Providers, Users and Regulators.
- 6 different Posters on BABS
- FAQ booklet on BABS
- 5 minutes BABS Animated Video



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