

# STEP-BY-STEP PROCEDURES FOR PERMIT APPLICATIONS

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Cape Town

DEA/CTFA Workshop on BABS Regulations



Biodiversity and Conservation



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## NEMBA CHAPTER 6 (SCOPE OF IBRs)

- Plants
- Animals
- Microorganisms
- Derivatives
- Genetic Resources
- Genetic Information
- Genetic materials

N.B Visit South African National Biodiversity Institute website to confirm the names of species that are indigenous to South Africa ~  
**[www.sanbi.org](http://www.sanbi.org)**



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*"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. 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.

# DISCOVERY PHASE

## 1 COLLECTING

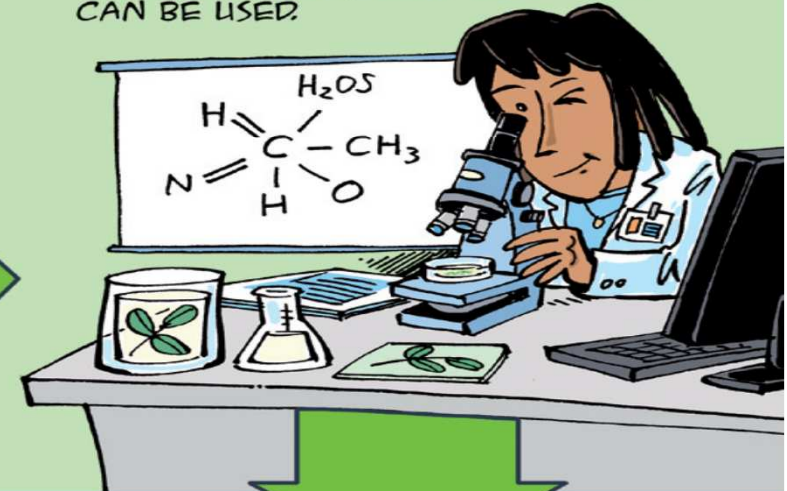
PLANTS, ANIMALS OR EVEN TINY CREATURES CALLED MICRO-ORGANISMS ARE COLLECTED FROM NATURE.



## 2

## SCREENING

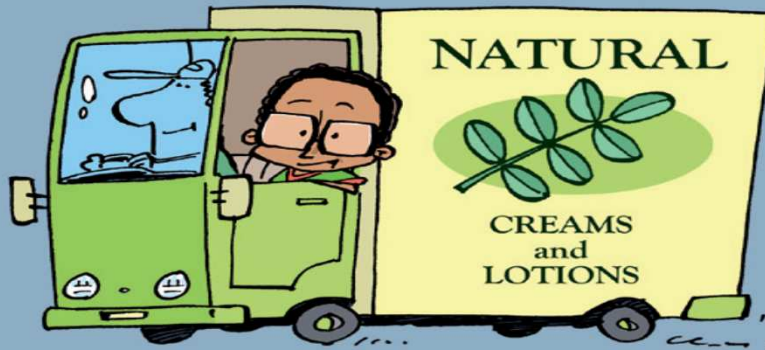
THESE ARE TAKEN TO A LABORATORY TO FIND OUT MORE ABOUT THEM, HOW THEY WORK AND HOW THEY CAN BE USED.



# COMMERCIALISATION PHASE

## 4 PRODUCTION

FINALLY, A PRODUCT IS MADE TO BE SOLD. A PATENT CAN BE REGISTERED - WHICH MEANS THAT NO ONE ELSE IS ALLOWED TO SELL THE SAME PRODUCT FOR A PERIOD OF TIME.



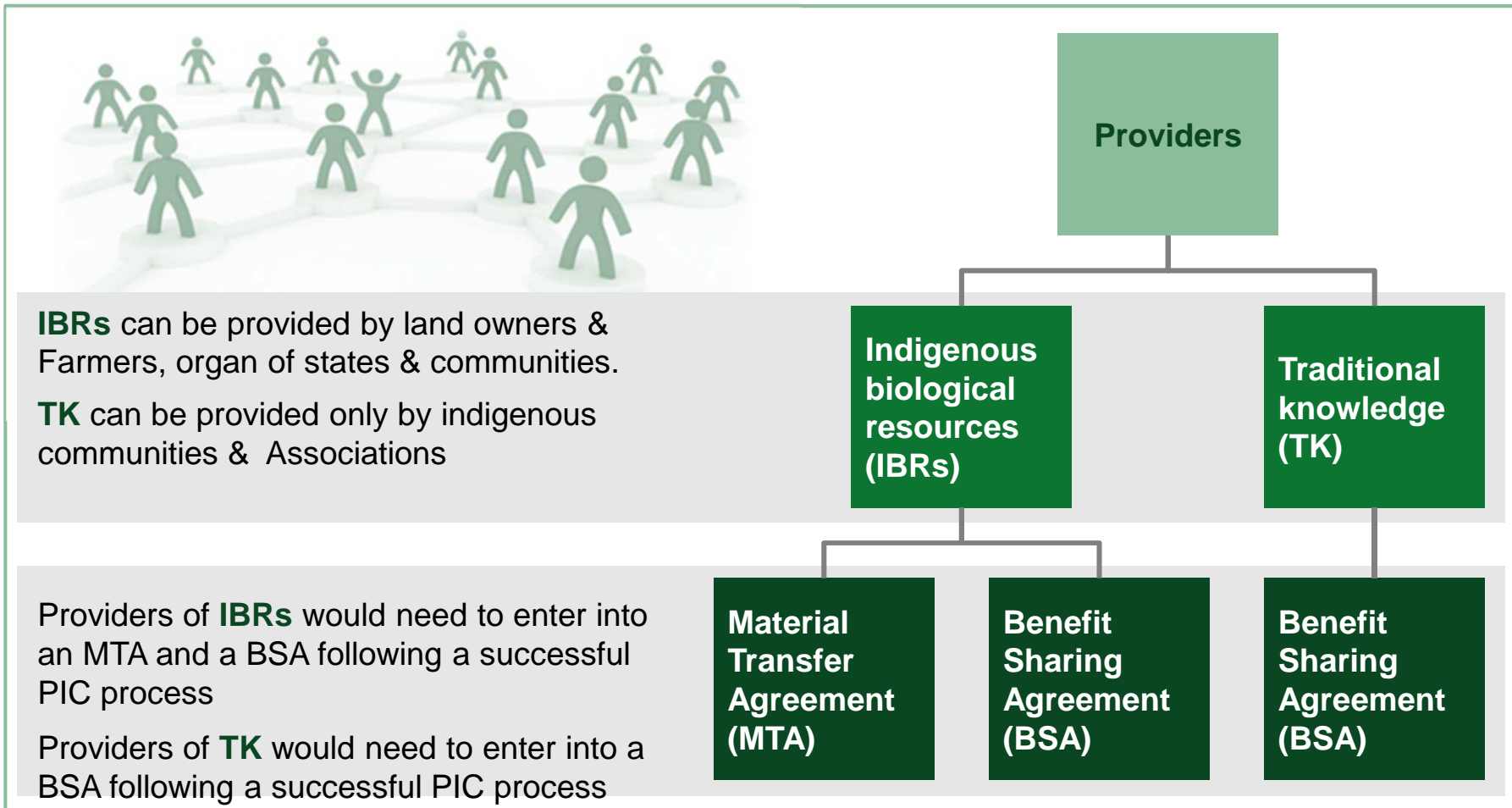
## DEVELOPMENT

## 3

IF USEFUL DISCOVERIES ARE MADE, SCIENTISTS WORK OUT HOW TO USE THEM IN A NEW WAY.



# PROTECTION OF RIGHTS OF PROVIDERS OF ACCESS TO IBSS & TK THROUGH MTA & BSA REQUIREMENTS



# FLOW CHART OF ABS PROCEDURE

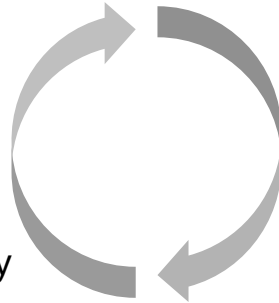
## Dept. of Environment Affairs

Bioprospecting Trust Fund/ Suspense Account

Issuing Authority (Minister)

Complete Permit Application form for:

- Commercialisation phase Bioprospecting
- Biotrade
- Export of IBR for Discovery phase bioprospecting



Grant Permit

Approve BSA &/ or MTA

Applicant

Benefit Sharing

Submit permit application, BSA &/or MTA

Obtain Prior Informed Consent, negotiate & Sign BSA &/or MTA



Provider Access to IBR/ Associated TK

Benefits paid



# PROCEDURES FOR PREPARING A PERMIT APPLICATION

- Source documents [www.environment.gov.za](http://www.environment.gov.za).
- Select & complete relevant Annexes to your project.
- Attach the signed permit application form, BSA(s) & MTA (s).
- Attach project summary/ background
- Pay the non-refundable permit application fee as prescribed in Annexure 4.
- Submit permit application documentation to DEA.
- Contact DEA officials for assistance, where necessary.



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## STEP-BY-STEP PROCEDURES

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

Guidelines for Providers,  
Users and Regulators





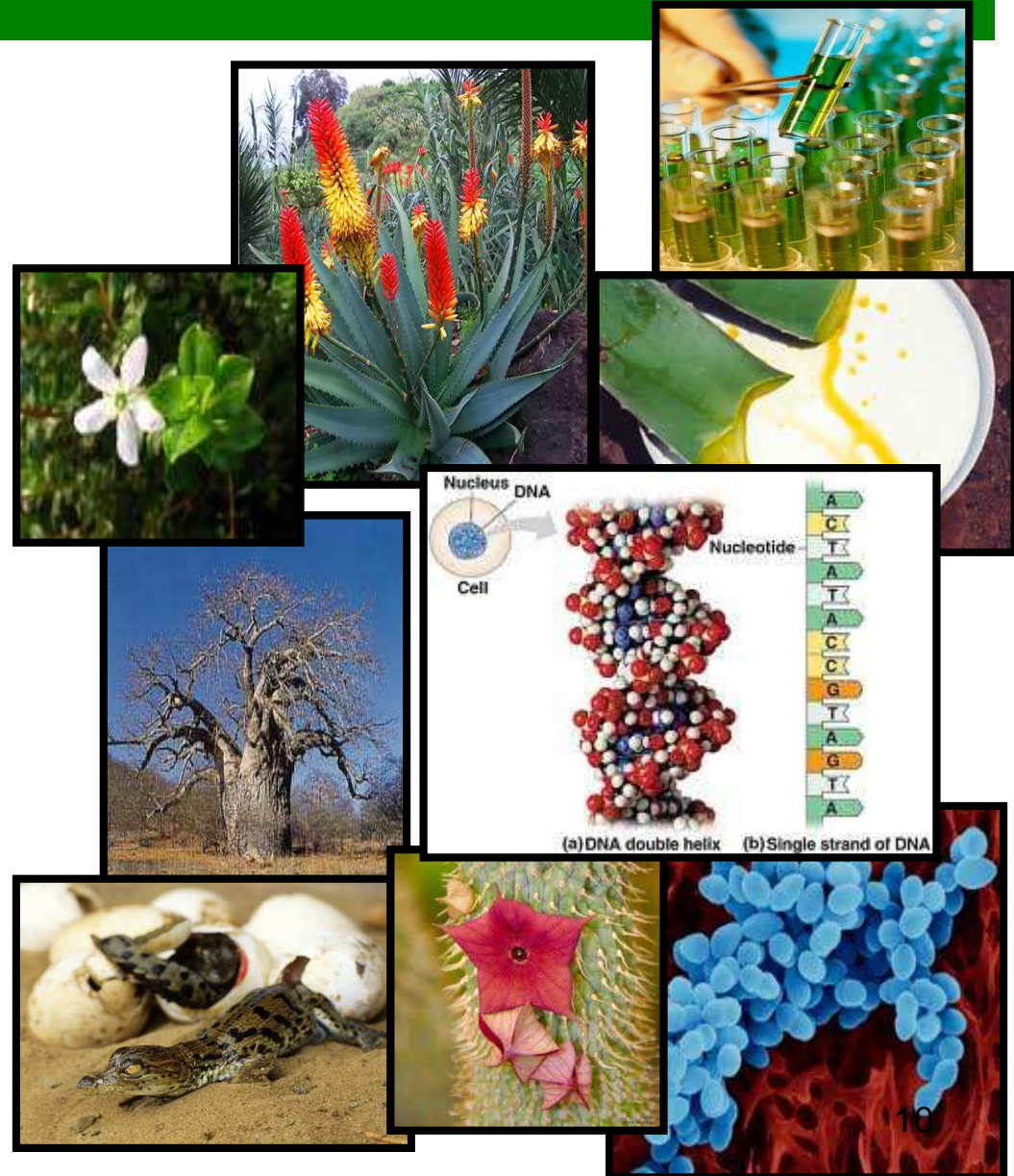
# PRE-APPLICATION INFORMATION CHECKLIST

1. What kind of biological resource am I planning to use?
2. Is it indigenous?
3. Where will I collect it, is it wild harvested or cultivated and where is it going?
4. Is there traditional knowledge associated with the biological resource?
5. What is being or has been done on it and what I am planning to do with it?



# WHAT KIND OF BIOLOGICAL RESOURCE?

- Plant
- Animal
- Microorganism
  
- Derivative = part, tissue, extract, chemical compound
  
- Genetic material = contains functional units of heredity



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# IS IT INDIGENOUS?

## Indigenous species

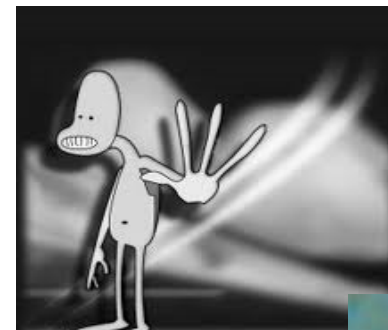
- Indigenous ≠ endemic
- Occurs or historically occurred in nature in RSA
- Excludes human genetic resources

activity



## Exotic / alien species

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



# WHERE WILL I COLLECT FROM?

## MTAs & BSAs required

- Supplier
- Community
- Land owner

## No material transfer agreement required

- Own land or cultivation

# WHAT AM I PLANNING TO DO WITH IT

- South African based activities
- International based activities
- Both National & International



# IS THERE ASSOCIATED TRADITIONAL KNOWLEDGE? BSA REQUIRED

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- ▶ Nervous system
- ▶ Immune & Infections
- ▶ Hormones & Libido
- ▶ Nutrition & Cleansing
- ▶ Bones & Muscles and pain relief
- ▶ Magnesium oil
- ▶ Heart, Brain & Energy
- ▶ Pet Range
- ▶ Chinese Herbs
- ▶ Single Herbs
- ▶ Bulk Herbs
- ▶ Mobility Scooters
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You are getting 100% Pure Hoodia Gordonii, nothing else added. You are not buying cheap quality - you are getting from the source! We guarantee top quality. We supply major pharmaceutical companies with this same Hoodia powder.

### WHY SHOULD I USE HOODIA GORDONII?

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In 1937, a Dutch anthropologist studying the San indigenous people in the Kalahari desert near what is now the South Africa-Namibia border noted that they sucked on the Hoodia plant as a hunger suppressant and thirst quencher. These bushmen did not eat on their two to three day hunts; instead, they munched on the stem of this succulent to suppress their hunger and thirst. The San people -known for their survival skills, rock art, trance-dancing and mystic symbiosis with their semi-desert or savannah environment -can trace their heritage back some 27,000 years on the basis of rock paintings drawn by their ancestors.

### SCIENTIFIC FACTS

Three decades ago, South African scientists at a government lab

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immune booster with  
cancer bush 50ml.  
R120.00



Infection Spray 50ml.  
R120.00



Bloodstream Spray  
50ml.

start



Completing a Biopros...

Google Image Result ...

Hoodia Gordonii Bush...

Document1 - Microsof...



# IDENTIFICATION OF TK HOLDERS

## Medium to Long term methods:

- National Recordal System by the Department of Science and Technology

## Interim methods:

- The following information points:
  - Medical Research Council website
  - SANBI website
- Desktop Research (Publications, Journals)
- Support from Government (DEA) for the identification of the TK holder.



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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](mailto:satmerg@uctgsh1.uct.ac.za)



UCT

Information from the Noristan, Pharmed 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](http://SAHealthInfo)



# How do I notify about Discovery phase Bioprospecting

## Discovery phase bioprospecting:

- ❖ Source documents [www.environment.gov.za](http://www.environment.gov.za)
- ❖ Complete Annexure 1
- ❖ Include non-disclosure agreement, where applicable
- ❖ Must also sign a commitment to comply with the requirements at the commercialisation phase of bioprospecting
- ❖ Contact DEA officials for assistance



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# HOW DO I APPLY FOR A PERMIT?

- ❖ Source documents [www.environment.gov.za](http://www.environment.gov.za)
- ❖ Use Annexure 2, 3 or 5
- ❖ Attach the signed BSA(s) (Annexure 12) and MTA (s) (Annexure 11), where applicable
- ❖ Pay the non-refundable permit application fee according to the structured fee relevant to your permit application
- ❖ Contact DEA officials for assistance



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# ROLE OF THE PERMIT ISSUING AUTHORITY

- Facilitate the negotiation process of the MTA & BSA upon request.
- Review the entire permit application documentation with technical support from the Bioprospecting Advisory Committee , focusing on:
  - *Species involved, Quantity & Sustainability*
  - *Steps taken to identify the relevant stakeholders;*
  - *Evidence for the full disclosure of information to the identified stakeholders (e.g letters, minutes or report of meetings etc);*
  - *Proof of PIC granted (e.g community resolution with full description of the community & contact details of their representative plus concluded MTA & BSA)*
  - *Proposed apportioning of benefits taking into consideration, the IPR, Investments already made by users or providers, availability of similar products in the market, level of exclusivity of the agreement etc.)*
- If not satisfied with the agreements, before making a final decision –
  - *Consult any person competent to provide technical advice on the agreement.*
  - *Conduct Public Participation on the non-confidential information of the concluded agreement.*



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## OBLIGATIONS OF PERMIT HOLDER

- Submitting biannual/ annual project status report;
- Applying for renewal/ amendment of permit;
- Is liable for the costs of mitigating or remedying the impact of the bioprospecting/ biotrade on the environment,
- Avoid selling, donating or transferring the IBR to a third party without a written consent of the Minister;
- Sharing non-monetary benefits due to Access Providers in terms of a BSA; and
- Payment of money due to Access Providers in terms of a BSA into the Bioprospecting Trust Fund, as required by section 85 (1) of NEMBA.

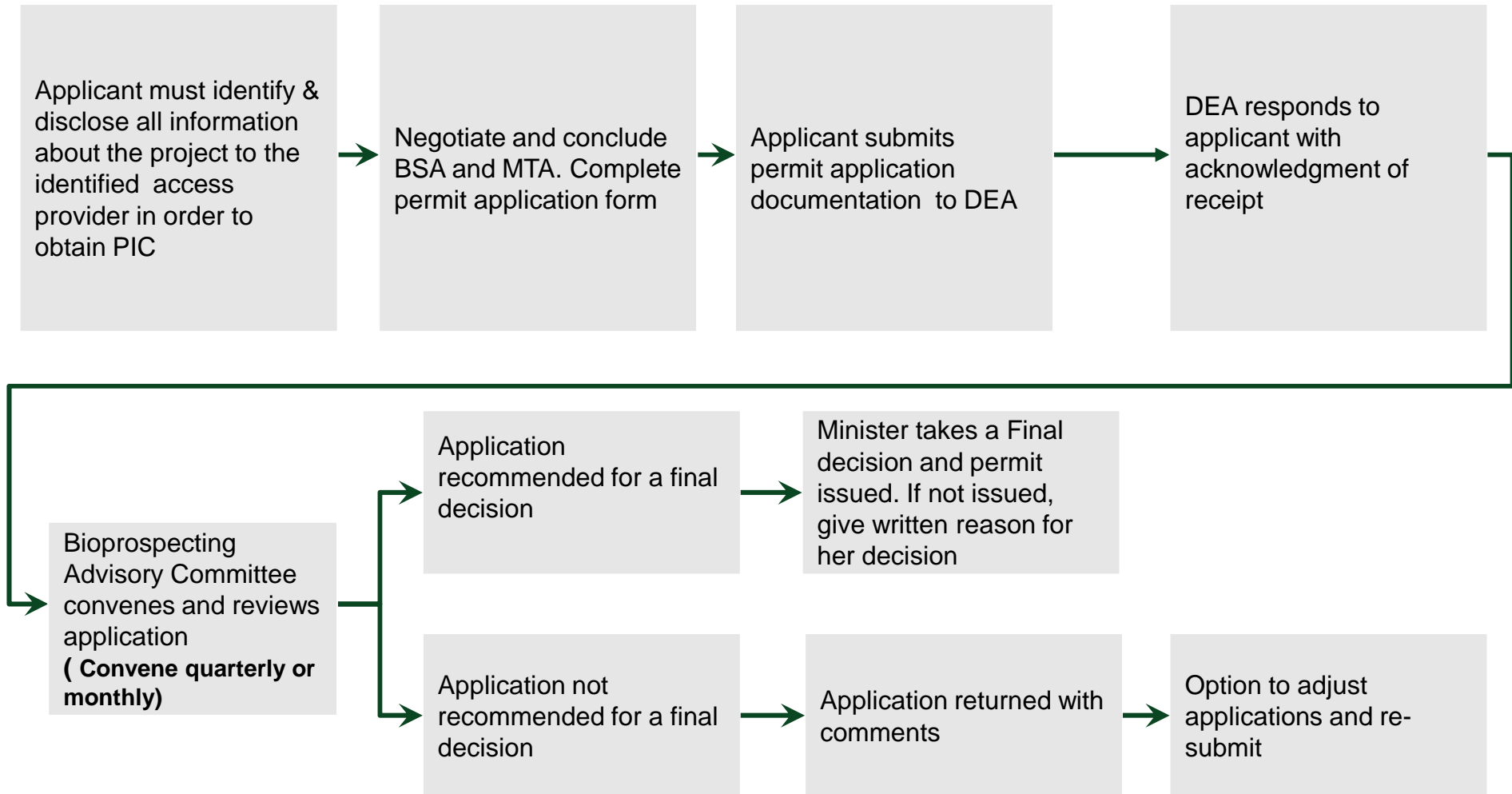


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# The permit application process begins long before the application is submitted to the Department of Environmental Affairs

**IBR** Indigenous Biological Resource **MTA** Material transfer agreement  
**TK** Traditional Knowledge **BSA** Benefit-sharing agreement



# CURRENT STATUS OF PERMIT ISSUED

- To date 52 permits issued
  - 22 are bioprospecting permits;
  - 17 are biotrade permits;
  - 13 are integrated biotrade & bioprospecting permits.
- Majority of these permits are for Cosmetic industry.



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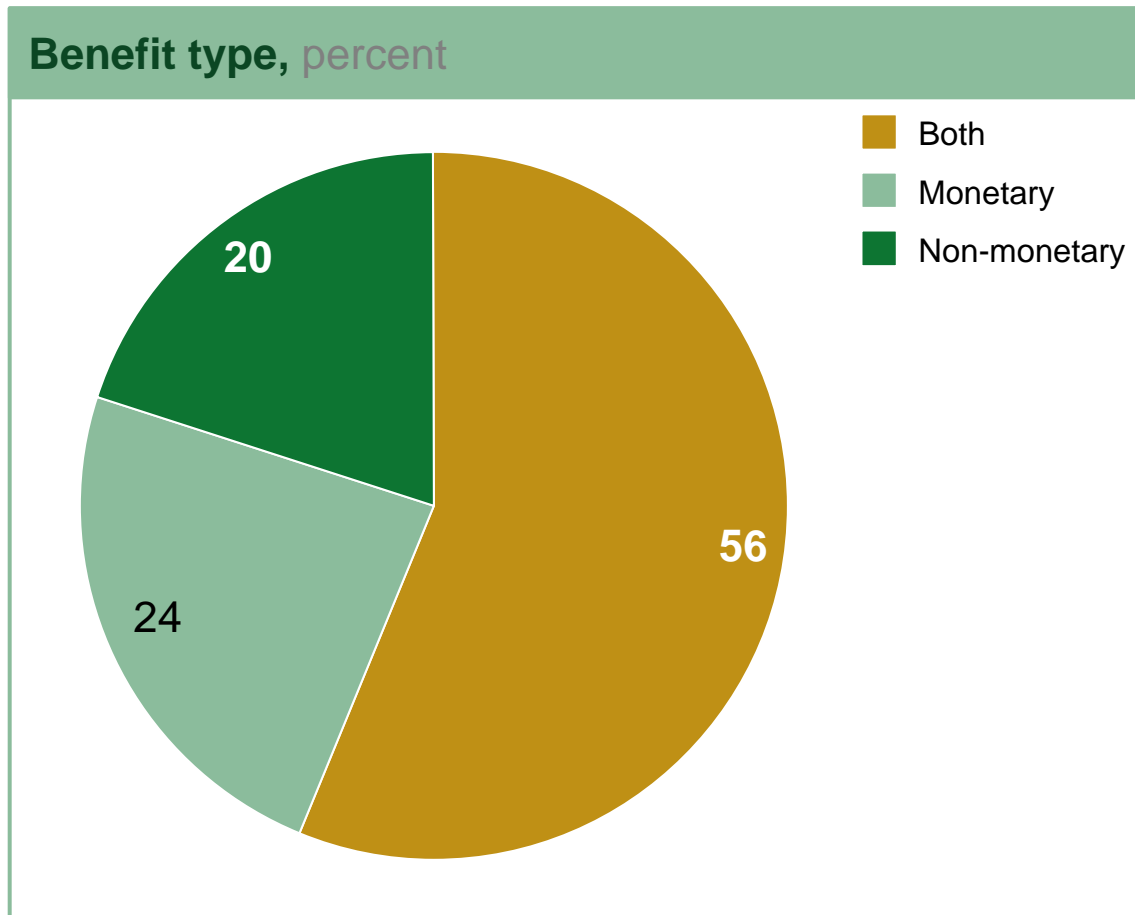
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# Monetary & Non-Monetary Benefits

- To date 79 Benefit Sharing Agreements have been Approved
- Permit applicants are open to a variety of benefit sharing options which range from **Short-Medium- Long Term Benefits**

Short Term	Medium Term	Long Term
Up-Front Payments	Access fees	License fees in case of commercialisation
Information	Milestone payments	Payment of Royalties
Species inventories	Environmental Education	Joint ventures
Access to collections	Training	Supply contracts
Acknowledgement of parties	Collaboration	Co-authorship of publications
	Strengthen capacity for technology transfer	Contribution to local economy
		Recognition and promotion of TK
		Livelihood benefits

# For permitted companies the bulk of entities use a combination of monetary and non-monetary benefits



- Key take aways**
1. Specific kinds of benefits are decided upon on a case by case basis by Parties
  2. Monetary benefits ranges from 1-10%



## CONTACT DETAILS

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DEA website [www.environment.gov.za](http://www.environment.gov.za)

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