# A business guide to access and benefitsharing (ABS)



Compliance with South Africa's biotrade and bioprospecting legal framework

Section 3

Discovery phase: Notification and permit applications



forestry, fisheries & the environment Department: Forestry, Fisheries and the Environment REFUBLIC OF SOUTH AFRICA







Implemented by: **GIZ** Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH This document is part of a series of knowledge products produced by the BioInnovation Africa (<u>BIA</u>) project in South Africa. Other BIA knowledge products and biotrade resources can be found on the joint <u>website</u> of BIA, ABioSA and the ABS Capacity Development Initiative.

Kruger Swart As<mark>soci</mark>ates (<u>KSA</u>) was commissioned to develop and publish this knowledge product in collaboration with BIA's South African partner, the Department for Forestry, Fisheries and the Environment (<u>DFFE</u>). This knowledge product is endorsed by the DFFE.

The BIA project is funded by the German Federal Ministry for Economic Cooperation and Development (BMZ) and implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH. Although every effort has been made to provide complete and accurate information, KSA and GIZ make no representations or warranties, express or implied, as to its accuracy at the time of use.

#### Adrie El Mohamadi

Component Manager - South Africa

BioInnovation Africa (BIA)

GIZ Center for Cooperation with the Private Sector (CCPS)

Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Adrie.elmohamadi@giz.de

Bioinnovationafrica@giz.de

www.giz.de www.abs-biotrade.info

### Introduction

This is **section three** of a six-part step-by-step guide for businesses working with biodiversity or engaging with bioprospecting and/or biotrade. It aims to ensure compliance with South African laws and regulations, in line with access and benefit-sharing principles and industry best practices.

**Section two** provided a guide to companies preparing to engage with laws, regulations, and permitting procedures when preparing ABS permit applications. **Section three** guides companies undertaking the discovery phase of bioprospecting, and applying for an export permit.

#### Section 3 is relevant if:

- You are an individual, company, research institution or organisation planning to conduct research into the potential properties or applications of indigenous South African biological or genetic resources in commercial products or processes
- Your research activities are still at an early or discovery phase, and if you are uncertain about the commercial value or properties of the resources
- You are conducting research in South Africa or exporting samples to other countries for research or bioprospecting discovery

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## Glossary

Term	Definition	
ABS	Access and benefit-sharing	
ABSCH	ABS Clearing House	
BABS	Bioprospecting, access and benefit-sharing	
BAC	Bioprospecting Advisory Committee	
BSA	Benefit-Sharing Agreement	
Bioprospecting	Bioprospecting in relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes (a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application; (b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or (c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation; or (d) the trading in and exporting of indigenous biological/genetic resources in order to develop and produce, such as medicines, industrial enzymes, food flavours, fragrances, cosmetics, colours, extracts and essential oils	
Biotrade	The buying and selling of milled, powdered, dried, sliced or extracts of indigenous genetic and biological resources for commercial exploitation	
CBD	Convention on Biological Diversity	
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora	
DFFE	Department of Forestry, Fisheries and the Environment	
DSI	Department of Science and Innovation	
dtic	Department of Trade, Industry and Competition	
IK	Indigenous knowledge means knowledge which has been developed within an indigenous community and has been assimilated into the cultural and social identity of that community, and includes (a) knowledge of a functional nature; (b) knowledge of natural resources; and (c) indigenous cultural expressions	
IKS Act	Protection, Promotion, Development and Management of Indigenous Knowledge Act (Act 6 of 2019)	
IRCC	Internationally-recognised certificates of compliance	
MAT	Mutually agreed terms	
MTA	Material Transfer Agreement	
NEMBA	National Environmental Management: Biodiversity Act (Act 10 of 2004)	
Organisations	An organised group of people with a particular and defined purpose, such as organisations representing traditional knowledge holders, organisations representing sectors, organisations who support sector development, etc.	
Organised group of traditional knowledge holders	Group of traditional knowledge (TK) holders mandated to present a wider group of TK holders who are organised and recognised by other TK holders such as the National Khoi and San Council of SA or the SA San Council	
PIC	Prior informed consent	
SANBI	South African National Biodiversity Institute	
TCE	Traditional cultural expressions are more tangible than the informal oral traditions relating to traditional knowledge, and include artefacts, folklore, myths, songs, poems, performances and handicrafts	
ТК	Traditional knowledge refers to the customary utilisation or knowledge of indigenous genetic and biological resources by an indigenous community or specific individual, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised by them, and include discoveries about the relevant indigenous genetic and biological resources by that community or individual	

## Key concepts

Definition	Examples
<b>Bioprospecting</b> in relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes: (a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application; (b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or (c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation; or (d) the trading in and exporting of indigenous biological/ genetic resources in order to develop and produce, such as medicines, industrial enzymes, food flavours, fragrances, cosmetics, colours, extracts and essential oils	Sourcing Buchu essential oil for use in the development of a new product, such as a perfume, would be considered bioprospecting. Bioprospecting would include collection of samples of different algae off the coast of Cape Town to search for bioactive compounds with potential to be used in pharmaceuticals. Collecting samples for a taxonomic study would <b>not</b> be considered bioprospecting, but rather basic research. Harvesting seaweed to dry and sell as a healthy food product would <b>not</b> be considered bioprospecting, but rather biotrade (see <u>section 4</u> , 'Key concepts').
The <b>discovery phase</b> of bioprospecting means 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	Collecting algae samples to search for bioactive compounds would fall within the discovery phase of bioprospecting. Screening samples of essential oil produced from different Pelargonium species to identify potential antioxidant properties would also fall within the discovery phase. Studies on a Pelargonium essential oil to develop and apply its antioxidant properties in cosmetic products would <b>not</b> form part of the discovery phase; this forms part of the commercialisation phase of bioprospecting (see <u>section 4</u> , 'Key concepts').

### Discovery phase: Types of applications

In the discovery phase of bioprospecting, activities in South Africa do not require a permit, but the national competent authority, the DFFE, must be notified – refer to 'Steps for compliance: Discovery phase notification process' below.

The export of indigenous biological resources or their parts or compounds for bioprospecting discovery phase activities requires an export permit from the DFFE, following notification – refer to 'Completing the Discovery Phase Notification form' below.

These two processes are outlined, step by step, below.

The following steps are required for notification of discovery phase activities

### Steps for compliance: Discovery phase notification process



#### Step 1: Gather information and supporting documents

- The person or entity making the notification must prepare and submit a detailed description of the project, including what activities will be undertaken, when, how, and by whom.
- Given that discovery phase activities often involve a range of different plants or other species, the notification process currently does not require prior informed consent (PIC), a Material Transfer Agreement (MTA) or a Benefit-Sharing Agreement (BSA). However, the person or entity making the notification is asked to explain whether the project is informed by any traditional or indigenous knowledge (TK/IK) and, if so, which sources have been consulted.
- Certified copies of the identity documents or passports of the bioprospecting project leader, and the person authorised to sign on behalf of the company making the notification, are required for the notification process.
- The DFFE has a checklist summarising all documents to be prepared for a Discovery Phase Notification, which must also be completed and signed. This checklist is included as Annexure F in <u>section 6</u>.



#### Step 2 : Fill out Discovery Phase Notification form (Annexure 1)

Annexure 1 of the BABS Regulations is a template for the Discovery Phase Notification form. It is a sevenpage document with three sections:

- Section A covers details of the person or entity making the notification
- Section B covers bioprospecting project information
- Section C has provisions committing the signatory to seek a Bioprospecting Permit if the project moves to the commercialisation phase.

For more guidance on Annexure 1, please see 'Completing the Discovery Phase Notification form' below. Annexure 1 is also available for review in <u>section 6</u>.

### Step 3 : Receive confirmation letter

An email from the DFFE serves as acknowledgement of receipt of discovery phase notification documents. After an internal assessment, an official acknowledgement letter is issued. This letter constitutes legal proof of the notification and establishes the conditions to be met by the person or entity conducting the discovery phase activities.

#### Step 4: Report and comply with other conditions

Conditions established in the official acknowledgement letter often include periodic reports, obtaining other relevant permits, as well as provisions restricting the transfer of samples to third parties.

### Completing the Discovery Phase Notification form



The Discovery Phase Notification form is completed on the prescribed form from the DFFE, Annexure 1, as referenced in <u>section 6</u>.

The notification form includes the sections discussed in detail below. The physical and online systems require the same forms to be completed.

	Template element	Explanation
А	Details of the discovery phase applicant	• This section includes details on the juristic or legal body making the application, including its full name, the country where it is legally registered and its registration number
		• It also requires the contact details of the person responsible for the application
		<ul> <li>It is possible that a natural person or individual can complete the notification form, but they still need to show affiliation to a juristic/legal body, and supply the details of this body</li> </ul>
	Bioprospecting	<ul> <li>All the information on the proposed project is shared in this section, and it needs to be backed up by the detailed proposal as referenced in Step 1 of 'Steps for compliance: Discovery phase notification process' above.</li> </ul>
		<ul> <li>This section needs to include the personal details of the project leader</li> </ul>
		<ul> <li>The following information needs to be reflected in terms of the project proposal:</li> </ul>
		- Title of the project
В		- Objective
В	project information	- Proposed methodology
		- Proposed timeframe
		<ul> <li>Details of the indigenous genetic and biological resource, as gathered during the preparation phase detailed in <u>section 2</u>, 'The resource'.</li> </ul>
		<ul> <li>Details on prior permits, including CITES, TOPS, and harvesting permits</li> </ul>
		<ul> <li>Details on the sponsor of the project and whether the sponsor is based in South Africa or abroad</li> </ul>
		<ul> <li>An overview of the TK/IK associated with the resource</li> </ul>
С	Commitment	This is a commitment signed by the applicant to comply with the permit requirements for the commercialisation phase, if the project enters this phase

### Discovery phase: Types of applications

### Steps for compliance: Discovery Phase Export Permit

#### Step 1: Gather information and supporting documents

- To apply for a Discovery Phase Export Permit, the discovery phase bioprospecting activities must also be described. The application must be accompanied by a copy of the official DFFE acknowledgement of the notification, or by the completed and signed Discovery Phase Notification form.
- Information required for the Discovery Phase Export Permit is detailed in 'Completing the Discovery Phase Export Permit form' below.
- The application must be accompanied by all relevant documents for PIC, MTAs and BSAs, so the negotiation processes outlined in <u>section 5</u>, 'Benefit-Sharing Agreement with traditional/indigenous knowledge holders', will need to be undertaken in advance of any application.
- Certified copies of the identity documents or passports are required for the project leader or the person authorised to sign on behalf of the company applying for the permit.
- A fee must be paid prior to submitting the application for a Discovery Phase Export Permit. The fee varies depending on whether a South African company is applying alone, or whether foreign companies are also applying. The fee is set in Annexure 4 (see <u>section 6</u>) at R200 per company which is party to the application.
- The DFFE has a checklist summarising all documents to be prepared for a Discovery Phase Notification, which must also be completed and signed. This checklist is included as Annexure F in <u>section 6</u>.

#### Step 2 : Fill out the application form for Discovery Phase Export Permit (Annexure 2)

Annexure 2 of the <u>BABS Regulations</u> is the template for the application for a Discovery Phase Export Permit. It lists 13 items of information required, including the purpose of the export, the recipient of the samples, and the amount and types of materials sent, etc. For more guidance on Annexure 2, please see 'Completing the Discovery Phase Export Permit form' below. Annexure 2 is also available for review in <u>section 6</u>.

#### Step 3 : Respond to any questions or queries

An email often serves as acknowledgement of receipt of a submitted application for a Discovery Phase Export Permit. Internal DFFE assessments may lead to follow-up questions or requests for clarification.

#### Step 4 : Report and comply with other conditions

The Minister of the DFFE makes the final decision on the application. If approval is granted, then the Discovery Phase Export Permit will be issued. An official ministerial approval letter is sent to the applicant, followed by the actual permit. The permit constitutes legal proof of the authorisation to export samples for the purpose of discovery phase activities. It also establishes the conditions to be met by the persons or entities involved, both in South Africa and abroad, for the duration of the permit.

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### Discovery phase: Types of applications

### Completing the Discovery Phase Export Permit form



The Discovery Phase Export Permit form is completed on the prescribed form from the DFFE, Annexure 2, as referenced in <u>section 6</u>.

The export permit application form has the following sections.

Template element	Explanation
	There are three kinds of permit:
Kind of normit	A new application
Kind of permit	• A permit renewal, in which case the previous permit number needs to be indicated
	• A permit amendment, in which case the previous permit number needs to be indicated
	This section includes details on the juristic or legal body making the application
	<ul> <li>Its asks for the name of the body, the country where the body is legally registered, and its registration number</li> </ul>
	• It also requires the contact details of the person at the body responsible for the application
Applicant information	<ul> <li>It is possible that a natural person or individual can complete the notification form, but they still need to show affiliation to a juristic/legal body, and supply the details of this body</li> </ul>
	<ul> <li>Two companies can apply as co-applicants to be the permit holder for one value chain. The applicant information in Section A, Annexure 5 (section 6) will be duplicated, but the remainder of the application will be as though there is a single applicant. Permits will then be issued in the names of both entities.</li> </ul>
Project leader	This includes the personal details of the project leader
Recipient of indigenous	• The personal details of the recipient of the resource are required. In the case where this is a company, it should be the details of the person able to legally represent the company.
biological resources being exported	<ul> <li>This section also asks for a short overview of the objective or purpose for which the resource is being exported</li> </ul>
Indigenous genetic and biological	<ul> <li>This section includes the details of the indigenous genetic and biological resource that the applicant is applying to receive a permit for</li> </ul>
resource	<ul> <li>All the information needed here would have been gathered during the preparation phase, as included in <u>section 2</u>, 'The resource'</li> </ul>

## How to prepare for ABS permit applications

Template element	Explanation
	There are two types of stakeholders that need to be included in this section:
	• <b>Access provider</b> , which is the party that gives access to the resource. This can include, but is not limited to, communal or private landowners, state institutions, etc. Information on access providers would have been gathered during the preparation phase as included in <u>section 2</u> , 'The resource'.
	• TK/IK holders, who are custodians of the knowledge associated with the use of the resource. This can include, but is not limited to, indigenous communities, individuals, associations or organisations of traditional healers or practitioners, etc. Information on TK/IK holders would have been gathered during the preparation phase as included in <u>section 2</u> , 'The resource'.
Stakeholders	Agreements concluded with these stakeholders must be indicated in this section and attached to the application. This can include:
	• Benefit-Sharing Agreements, as detailed in <u>section 5</u> , 'Benefit-Sharing Agreements with access providers' and 'Benefit-Sharing Agreements with traditional/indigenous knowledge holders'
	<ul> <li>Material Transfer Agreement, as detailed in <u>section 5</u>, 'Material Transfer Agreement with the provider of the resource'</li> </ul>
	<ul> <li>Community Resolutions, as detailed in <u>section 5</u>, 'Community Resolution', inclusive of evidence of prior consent being granted</li> </ul>
	• Evidence that the nature of the business or project related to the indigenous genetic and biological resource covered under the permit application has been shared
Signatures	The project leader as indicated in the application will sign

### Useful tips



Raise awareness in your company of the need for and importance of notifying the DFFE of early-stage research into indigenous biological or genetic resources. If possible, build notification of discovery phase activities into the research and development stage. Notification is a simple process that can ensure a solid start to your project. It activates an incentive through discounted permit application fees during the commercialisation phase of bioprospecting.



If your research project involves partners abroad, it is often necessary to not only to list them as recipients in the Discovery Phase Export Permit application form, but also to include them as coapplicants. Remember, requirements under the BABS regulations also apply to companies conducting research and development activities abroad.



Requirements for MTAs and BSAs when accessing biological resources for export in the discovery phase of bioprospecting may impact the selection of local partners. It is useful to work with partners who are aware of biodiversity-related rules, and who are willing to support your company in the process.