

# A business guide to access and benefit-sharing (ABS)



Compliance with South Africa's biotrade and bioprospecting legal framework

## Section 4

Commercialisation phase:  
Biotrade, Bioprospecting and  
Integrated Permit Applications



forestry, fisheries  
& the environment

Department:  
Forestry, Fisheries and the Environment  
REPUBLIC OF SOUTH AFRICA



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# Introduction

This is **section four** 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 three** provided a guide to companies undertaking the discovery phase of bioprospecting, including the process for notifying the Department of Forestry, Fisheries and the Environment (DFFE), and applying for an export permit. **Section four** explains the steps which must be completed when applying for a Biotrade, Bioprospecting or Integrated Biotrade and Bioprospecting Permit, and the procedures followed by bodies such as the DFFE and the Bioprospecting Advisory Committee.

**Section four** is relevant if you are an individual or company involved in the commercial trade of indigenous biological or genetic resources. It is applicable when the resource is processed from its natural state, e.g. dried and traded in bulk to be integrated into consumer products further down the value chain. It is also applicable when product development takes place, when value is added to the resource, and/or when the final product is produced, e.g. extracting, packing, etc. A biotrade permit is needed if the product is sold in either national or international markets.

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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
TK	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
TOPS	Threatened or protected species

# Key concepts

Definition	Examples
In relation to biological resources, <b>commercialisation</b> relates to the following activities: (a) filing of a complete intellectual property application, whether in South Africa or anywhere else; (b) obtaining or transferring any intellectual property right or any other right; (c) commencing product development, including the conducting of market research and seeking pre-market approval for the sale of resulting products; (d) the multiplication of indigenous biological resources through cultivation, propagation, cloning or other means to product and develop products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, extracts and essential oils; (e) trading in and exporting of indigenous biological resources to develop and produce products such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, extracts and essential oils; (f) commercial exploitation	<p>When a nasal spray developed from Rooibos extract is tested in clinical trials to prove its anti-allergic properties.</p> <p>If <i>Helichrysum spp.</i> is cultivated from plant material found in the wild but grown at scale for distillation of oils for the flavour and fragrances industry.</p>
<b>Commercial exploitation</b>	Commercial exploitation means engaging in any bioprospecting activity with the intention of making profits.
The <b>commercialisation phase</b> of a bioprospecting project 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 sufficiently established to begin the process of commercialisation.	When research on the anti-allergic properties of Rooibos is completed and nasal spray is developed and put on the market.
<b>Biotrade</b> means the buying and selling of milled, powdered, dried, sliced or extracts of indigenous genetic and biological resources for further commercial exploitation.	<p>Biotrade refers to the collection, production, transformation, and commercialisation of goods and services derived from indigenous biodiversity (species and ecosystems) under the criteria of environmental, social and economic sustainability.</p> <p><b>Example:</b> Harvesting seaweed to dry and sell in the market as a healthy food product or wild harvesting <i>Helichrysum spp.</i> to be distilled into oil and sold in bulk to fragrance manufacturers.</p>
Biotrade Permit	If it is in natural state, or processed from natural state, and traded in bulk.
Bioprospecting Permit	If research or product development activities are undertaken, when value is added to the resource, and/or when a final product is produced (extracting, packing, etc.). This kind of permit also allows for development and production of products which are ready for consumption.
Integrated Biotrade and Bioprospecting Permit	This should be applied for when activities include both biotrade and bioprospecting as defined above, i.e., manufacturing and trade in semi-finished and finished products.

# Key concepts

Definition	Examples
<p><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</p>	<p>Bioprospecting covers activities that involve searching for and using plants, animals, fungi, or microorganisms (or their parts, biochemical compounds, or genetic material) to develop commercial products and processes.</p> <p>Sourcing Buchu essential oil for use in the development of a new product, such as a perfume, would be considered bioprospecting.</p> <p>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.</p> <p>Harvesting seaweed to dry and sell as a healthy food product would <b>not</b> be considered bioprospecting, but rather biotrade.</p>

Which parties in the biotrade value chain require a permit?

- Current legislation requires that every party in the value chain must apply for a permit.
- This is applicable to all parties, including brand owners who are manufacturing finished products to be sold to consumers.
- The only party in the chain that is not legally required to apply for a permit is the retailer.
- For example, if a supermarket chain has a private label Rooibos brand, it will be packed for them by a contract packer. In this case the permit is required from the contract packer and not from the retailer. The party who owns the floor space where product is sold is not required to have a permit.

# Steps for compliance: Biotrade, Bioprospecting and Integrated Biotrade and Bioprospecting Permit Applications



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

- Before your permit application, it is important that you gather the information set out in [section 2](#).
- Specific information required for the Biotrade, Bioprospecting or an Integrated Permit is detailed below, 'Completing the 'Commercialisation Phase' of the Bioprospecting Permit Application form'.
- A Biotrade, Bioprospecting or an Integrated Permit must be accompanied by all relevant documents relating to Material Transfer Agreements (MTA) and Benefit-Sharing Agreements (BSA). This means the negotiation processes outlined in [section 5](#), 'Benefit-Sharing Agreement with traditional/indigenous knowledge holders', will need to be undertaken prior to any application.
- Certified copies of the identity documents or passports are required for the applicant and, if necessary, the person authorised to sign on behalf of the company applying for the permit.
- A fee must be paid prior to submitting the permit application. The fee varies depending on the size and turnover of the company, and is set out in Annexure 4 in [section 6](#). A proof of payment must accompany the application form.
- The DFFE has a checklist summarising all documents to be prepared for a Biotrade, Bioprospecting or an Integrated Biotrade and Bioprospecting Permit. The checklist must also be completed and signed. It is included as Annexure E in [section 6](#).



## **Step 2 : Fill out the application form for an Integrated Biotrade and Bioprospecting Permit**

Annexure 5 of the BABS Regulations is the template for the application for a Biotrade, Bioprospecting or an Integrated Biotrade and Bioprospecting Permit. It is an eight-page document with twelve items of information required, including details on the applicant and collaborators, the type and amounts of the resource applied for, involved stakeholders and a business plan or business summary. For more guidance on Annexure 5, please see 'Completing the 'Commercialisation Phase' of the Bioprospecting Permit Application form' below. Applicants must be sure to initial the application on all pages, including the supporting documentation. Annexure 5 is available for review in [section 6](#).



## **Step 3 : Respond to any queries**

An email from DFFE serves as acknowledgement of receipt of a submitted application for a Biotrade, Bioprospecting or an Integrated Biotrade and Bioprospecting Permit. This email will include an official letter with a permit application reference number. The email or letter will also outline whether additional information or documentation is required following an internal assessment. There may also be a request for clarification. If the permit application meets the minimum requirements in terms of the BABS Regulations, it is brought before the Bioprospecting Advisory Committee (BAC), which is mandated to conduct the technical evaluation of permit applications and their associated agreements.



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

The Minister of the DFFE makes the final decision on the permit application, based on recommendations from the BAC. If the application and associated MTA/s and BSA/s are approved, the permit will be issued. An official ministerial approval letter is sent to the applicant, followed by the permit. The permit constitutes legal proof of authorisation to commercially trade in indigenous biological resources included in the application. It also establishes conditions to be met by the persons or entities involved for the duration of the permit.

# Steps for compliance: Biotrade, Bioprospecting and Integrated Biotrade and Bioprospecting Permit Applications



## **What is the Bioprospecting Advisory Committee and what is its role in ABS?**

The BAC consists of representatives from organisations active in the biotrade sector, including:

- South African National Biodiversity Institute (SANBI)
- South African National Parks (SANParks)
- Provincial nature conservation agencies
- Representatives from national government departments, including DFFE, Department of Science and Innovation, Department of Trade, Industry and Competition, Department of Health and Department of Cooperative Governance and Traditional Affairs

*The BAC is a group of experts who work together as a panel to advise the DFFE as the permit issuing authority. It offers its combined expertise to inform the Minister's decision.*

A consistent observation by previous applicants is that the period can be lengthy between submission of the permit application and the permit being awarded. It may help to understand that the permit application needs to pass the technical assessment and review process of the BAC and the DFFE, and may potentially require specific amendments or additional documentation/information. The figure included on page 9 is an overview of the process for permit application and review.

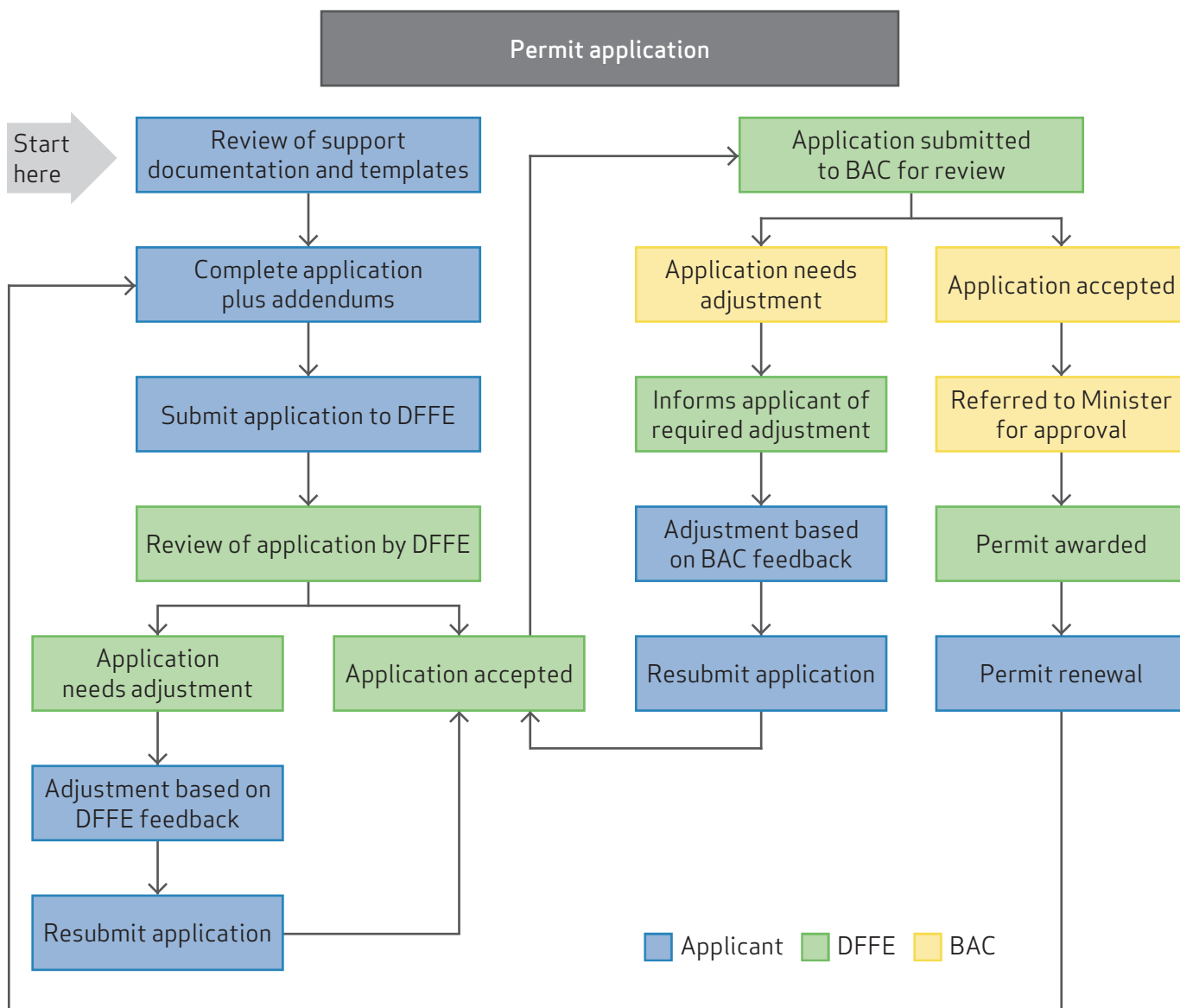


## *How applicants can make the process more efficient*

- Prepare well and include detailed information
- Get help from your industry association or business support organisation
- Make sure you have a contact person at the DFFE so you can follow-up on the status of your application
- If adjustments are required, attend to them as soon as possible



# Steps for compliance: Biotrade, Bioprospecting and Integrated Biotrade and Bioprospecting Permit Applications



Process for permit application and review



## Reasons why applications may be returned by the DFFE or BAC

- Applications are not fully completed prior to submission
- All pages of the application and supporting documentation are not initialled
- Information on the resource is not aligned between the permit application form, the MTA and the BSA
- The roles of collaborators are not specified
- The project summary does not adequately consider environmental issues

# Completing the ‘Commercialisation Phase’ of the Bioprospecting Permit Application form



The Biotrade, Bioprospecting and Integrated Biotrade and Bioprospecting Permit Applications must be completed on Annexure 5 (BABS). The application is supported by the agreements as referenced in [section 5](#), including the MTA, the BSA and the Community Resolution, if relevant.

*The permit application form has the following sections:*

Section	Template element	Explanation
	Type of permit	<p>There are three types of permits for commercially-traded products. Applicants need to ensure the correct permit is applied for. These are listed below, and explained in more detail in ‘Key concepts’ above:</p> <ul style="list-style-type: none"> <li>• Biotrade Permit</li> <li>• Bioprospecting Permit</li> <li>• Integrated Biotrade and Bioprospecting Permit</li> </ul>
A	Applicant information	<ul style="list-style-type: none"> <li>• This section requires contact and identification details for the applicant.</li> <li>• There is a section for an individual contact who should be a person able to legally represent her/himself, or the company (if relevant).</li> <li>• There is also a section for company details.</li> <li>• Under South African law, the applicant must be a registered company or natural person.</li> <li>• Both sections must be completed.</li> </ul>
B	Collaborators	<ul style="list-style-type: none"> <li>• This section includes contact and identification details for companies or individuals collaborating with or providing core services to the applicant, e.g., where another business is a contract packer on behalf of the applicant.</li> <li>• This can include contract manufacturers, branding companies, marketing companies, core service providers to the applicant, etc.</li> <li>• The role of each collaborator or service provider should be specified.</li> <li>• If the applicant is not involved with collaborators, this section does not have to be completed.</li> </ul>
C	Discovery phase bioprospecting	<ul style="list-style-type: none"> <li>• This section will only be completed if the applicant has submitted a Discovery Phase Notification to the DFFE, as detailed in <a href="#">section 3</a>, ‘Steps for compliance: Discovery phase notification process.’</li> </ul>
D	Indigenous genetic and biological resource	<ul style="list-style-type: none"> <li>• This section includes details of the indigenous genetic and biological resource to be covered by the permit.</li> <li>• All the information needed would have been gathered during the preparation phase as included in <a href="#">section 2</a>, ‘The resource.’</li> </ul>

# Completing the ‘Commercialisation Phase’ of the Bioprospecting Permit Application form

Section	Template element	Explanation
E	Applications for other permits	<ul style="list-style-type: none"> <li>• This section includes details on any other permit applications submitted in respect of the resources included in the permit application.</li> <li>• This can include, but is not limited to:               <ul style="list-style-type: none"> <li>- Collection or harvesting permits applied for in terms of the National Forests Act (Act 84 of 1998), if the resource is on the list of indigenous protected trees</li> <li>- CITES permit, required if the resource is on the CITES list</li> <li>- TOPS permit, required if the resource is on the TOPS list</li> <li>- Harvesting permits to be obtained from provincial authorities</li> </ul> </li> <li>• Phytosanitary certificate (where applicable).</li> </ul>
F	Stakeholders	<ul style="list-style-type: none"> <li>• There are two types of stakeholders to be included under this section:               <ul style="list-style-type: none"> <li>- The access provider, who is the party that grants 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 <a href="#">section 2</a>, ‘The resource’.</li> <li>- Traditional/indigenous knowledge (TK/IK) holders, who are custodians of the knowledge on the product. 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 <a href="#">section 2</a>, ‘The resource’.</li> </ul> </li> <li>• All agreements concluded with these stakeholders must be indicated in this section and attached to the application. These can include:               <ul style="list-style-type: none"> <li>- BSAs, as detailed in <a href="#">section 5</a>, ‘Benefit-Sharing Agreement with access providers’ and ‘Benefit-Sharing Agreement with traditional/indigenous knowledge holders’</li> <li>- MTAs, as detailed in <a href="#">section 5</a>, ‘Material Transfer Agreement with the provider of the resource’</li> <li>- Community Resolutions, as detailed in <a href="#">section 5</a>, ‘Community Resolution’, including evidence of prior informed consent (PIC) being granted</li> <li>- Evidence that the nature of the business or project has been shared</li> </ul> </li> </ul>
G (1)	Traditional knowledge	<ul style="list-style-type: none"> <li>• This section describes the TK/IK associated with the resource</li> <li>• Information on TK/IK would have been gathered during the preparation phase as included in <a href="#">section 2</a>, ‘Traditional and indigenous knowledge holders’</li> <li>• TK/IK can be in written form, but may also be part of the oral history of the TK/IK holders.</li> </ul>

# Completing the ‘Commercialisation Phase’ of the Bioprospecting Permit Application form

Section	Template element	Explanation
G (2)	Business plan or project summary	<ul style="list-style-type: none"> <li>• This is a section that may challenge many applicants, but should be an overview of planned or implemented activities related to the use of the resource.</li> <li>• This description will be unique to the application, as every business is different. Think about the activities of the business, the values of the business, and how these contribute to the economy and provide a public benefit, while at the same time showing care for the environment and biodiversity.</li> <li>• Include the following information: <ul style="list-style-type: none"> <li>- The intention of the business or project, the activities that will be implemented and what the outcomes of these activities will be</li> <li>- The benefits to the economy and benefits related to public interest</li> <li>- The environmental benefits proposed, but also the impact that the business or project may have on the environment, and how this impact will be mitigated. This should include information on how the resource will be sustainably sourced, and an indication of the tangible benefits that the biotrade/bioprospecting project will provide or contribute to promoting conservation of biological resources.</li> <li>- It is very important to outline how the waste generated through this project will be managed</li> </ul> </li> </ul>
H	Recipients of indigenous genetic and biological resource	<ul style="list-style-type: none"> <li>• For the protection of the resource/s, it is also important to monitor the movement of the resource beyond the permit applicant.</li> <li>• This section focuses on the next point in the value chain the resource will move to, with details of trading partners.</li> <li>• If these partners are local, the DFFE will provide oversight to ensure they are also compliant with the BABS permitting system.</li> <li>• Once a permit is granted, the DFFE will make this information available to the ABS Clearing House. An internationally-recognised certificate of compliance will then be issued with evidence of PIC and mutually agreed terms.</li> </ul>
I	List of annexes or additional information	<p>List all applicable annexes here. These can include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Copies of permits, as indicated in section E of the application.</li> <li>• Agreements concluded with stakeholders, as indicated in section F of the application.</li> <li>• Annex or Addendum to the concluded agreements, if relevant.</li> <li>• A detailed business model, if relevant.</li> </ul>
J	Signatures	The applicant in section A needs to sign the permit application. The form must include the initials of the applicant on all pages.

## Useful tips



Ensure that personnel in your business who will be involved in the completion of the Biotrade, Bioprospecting or Integrated Biotrade and Bioprospecting Permit application are competent to provide the required information.



Ensure the application has been initialled on all the pages by the applicant/s.



Ensure the MTA/s and BSA/s are signed by both parties, and include the initials of the signatories on all pages.



Preparing well and completing the application thoroughly will avoid delays in reviewing and issuing the permit.



Be active in your follow-up after the permit submission to make sure that you monitor progress and are able to communicate to partners and clients if requested.



The negotiation of ABS agreements can be time consuming, so ensure you start this process as soon as possible. If you have difficulty in identifying the relevant TK/IK holder/s, follow the process as set out in [section 2](#), 'Traditional and indigenous knowledge holders'.



Bear in mind that the application and attachments exist to allow the BAC Secretariat to make your case to the BAC on behalf of your business.