Guidance document

The Role of Industry in Streamlining Bioprospecting and Biotrade Permit Applications











Imprint

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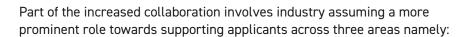
1. Introduction



When the bioprospecting and biotrade permitting system was first implemented this was a new process for both government and industry and at times it was reported that the permitting process was a long and complicated one. While the permitting system was conceptualised with care and in alignment to the responsibilities of the government under the Nagoya Protocol, the implementation of it presented some challenges that at times resulted in delays. The Department of Forestry Fisheries and the Environment (DFFE) invested time in streamlining systems and procedures to improve bioprospecting and biotrade permit applications.

Parallel to the gradual development of systems, industry and the DFFE have also over time established an increasingly collaborative relationship and approach to how permit applications are approached. This document details how industry can collaborate with the DFFE to further support streamlined implementation of the bioprospecting and biotrade permitting system.

2. Areas of industry support







Prior to submission by ensuring that permit applications are thoroughly prepared and completed before submission to DFFE.



During the review through active engagement and liaison with the DFFE to facilitate open lines of communication and more efficient resolution of issues as they arise.



Post submission to industry members towards interpreting needed corrections arising from the permit review process.

Over time it became apparent that these actions from industry and increased collaboration with the DFFE can significantly contribute to streamlining the process. The lessons learnt from this approach are captured in this document. To this end the purpose of this document is to:

- Support the industries and industry organisations to achieve uniformity in their applications and to submit as a constituent for batched assessment by the DFFE and the BAC
- Provide stepwise guidance to the industry stakeholders on the completion and submission of the permit applications
- Enhance clarity on the various checkpoints and milestones prior to submission; during the review through active engagement and liaison with DFFE and post submission.
- Provide clarification for respective industry focal points/associations on how they can support business within their industry to submit permit application in a streamlined manner



3. Industry Support for permit applications

Over the years a strong support network has emerged within the biotrade sector. Specifically, there are now a number of industry organisations with strengthened abilities to identify priorities and build capacity to act on both opportunities and challenges faced by members. Additionally, due to the rise of collective action, and cross learning among industry associations, there is also a group of industry

organisations working together on a range of targeted topics in the sector.

Moreover, the sector has multiple skilled consultants and biotrade businesses who are leaders in their industry and key contributors towards the diverse ecosystem in the biotrade sector.

As mentioned in the introduction, one of the challenges faced by industry members is with the permit application process and as capacity of industry organizations and networks increased, they also started to assist industry members in this area. Below is a summary of steps that industry organisations or other support structures can take to support industry members in the permit application process to ensure that this is a faster and more streamlined process.



The first step in the process is for industry representatives to reach out to the DFFE and introduce themselves as the contact point for this type of support. This model is in its essence based on collaboration between the DFFE and industry and industry representatives need to invest in building this collaborative relationship with the DFFE where it does not yet exist.



Secondly, it is important that industry members understand what needs to be considered and included in the permit application. It will make the support function of the industry representative a lot easier. To achieve this, knowledge and guidance can be shared with industry members on how applications need to be completed, or a guidance example of the permit application forms can even be developed and shared with members.



Once information has been shared with industry members, they can complete their own application forms and they then share this with the industry organisation, representative or support person as a first check point.



All applications are then checked for correct information, consistency and that the correct addenda are attached and if further work on the applications are needed, this is communicated to the applicant, and they are supported in making the corrections and additions.



Once the full pack of applications are ready and checked, the industry organisation or representative liaises with the DFFE BABS unit to inform them that they are ready and enquire about a suitable date where all the applications can be reviewed by the Bioprospecting Advisory Committee (BAC). Experience showed that if the BAC is presented with a set of applications all from the same industry, this makes the task of review so much easier and faster and is good practise to follow.

3. Industry Support for permit applications



The DFFE BABS unit will then communicate a date for submission that allows them to do the internal checks required prior to submission to the BAC. This is normally one month before the sitting of the BAC to allow corrections to applications if any are still needed.



The industry organisation or representative then in turn communicates to the industry that the applications need to be submitted by a certain date and provides the correct contact details to be used in submission. It is good practise to include the industry representative in communication when the submission is made, since then they stay informed of the process between the DFFE and the applicant and is able to support where needed.



Support is then provided by both the DFFE and the industry representative to make the last corrections and adjustments and get the applications ready for the review by the BAC.



Once the applications are then reviewed by the BAC, the industry organisation will again support with the submission of any outstanding corrections.



Lastly the industry organisation or representative liaises with the DFFE on the status of the application and when the applicant can expect to receive their permit.

4. Checkpoints in the application



With the completion of applications, the following considerations and checkpoints should be kept in mind.



4.1 Administrative considerations

- Permit application must be submitted to the BABS unit two weeks prior to the BAC sitting so that the unit has sufficient time for the implementation of due diligence processes. Submitting the application one week before the BAC sitting increases the chances of the application being considered at that sitting.
- The BABS Regulation states that once the DFFE has provided feedback on a permit application received, the applicants have 20 working days to respond to feedback. If this period is not observed, the DFFE may view the application as withdrawn based on the Regulation. Currently the DFFE implements flexibility in implementing this requirement, but it is good for applicants to be aware of this allowed time period.
- When a business with active permits is bought by a third party, the permits are not transferable, but new applications will need to be submitted due to new legal entity, business and contact person information.



4.2 Good practises

- Be transparent, truthful and accurate in the permit application. Remember
 that the DFFE can always visit the site to verify the information shared in permit
 applications and then it is important that they see onsite what was reflected
 in the permit application. If they find misalignment between the application
 and what is observed in the site visit, the application will be referred back for
 adjustment and the permitting process delayed.
- Information must be shared as comprehensively as possible. This will prevent the DFFE or the BAC returning the application with requests for more information.
- Consistency between Annexes 5, 11 and 12 is very important. For example, the same details for the permit applicant, the access provider and the traditional knowledge holders must be reflected in all the documents. The volumes reflected in Annexes 11 and 12 must be collectively indicated in Annex 5.
- All pages of the application must be initialled and signed as required.
- In the case where scans are submitted this must be legible.



4.3. Guidance on Annexure 5

Section	Guidance
Kind of permit	Here it is important to select the correct one:
	 Select Biotrade permit if the company is only involved in trading semi-finished products from indigenous biological resources to local or international market. i.e. Extracts, Essential oil, Crystals and others.
	Select Bioprospecting permit if the company is involved in the utilisation of indigenous biological resources in the manufacturing and production of finished commercial products i.e. Skin care products, Emulsifiers, Cosmetic, Fragrance and others. Note that this kind of permit also allows ones to export finished commercial products internationally.
	 Select integrated biotrade and bioprospecting permit if the company is involved both producing of semi-finished products (essential oil) and finished commercial products (Body care products, Fragrances).
	If the business is registered as an exporter or for value added tax (VAT) include the correct numbers
A: Applicant	Include the details of the correct contact person in A1
information	If the permit applicant is a company, include the details of the company and importantly the registration number of the company in Section A3
B: Collaborators	 In Section B4 reference is made to collaborators. Collaborators are other parties that the applicant works with who play a key role in manufacturing that allows the permit applicant to bring their product to market.
	For example if someone distils oil on behalf of the applicant, if someone packs the final product sold by the applicant, etc.
	Also remember that when a collaborator is indicated here, their role should be clearly included in Section G14 for the Business Plan or Project summary.
C: Discovery Phase Bioprospecting	Section C is only applicable and should only be completed if the business has a Discovery Phase permit
D: Indigenous genetic and biological resources	Section D9 must be carefully completed since unclear or incomplete information in this section is often why applications are returned:
	Scientific and common names: indicate both the scientific and common name, for example Agathosma betulina and Buchu
	Part of resource to be utilised: Clearly indicate which part of the resource you intend to use e.g. leaves, roots or the whole plant
	Physical state of resource: this is the commercial form of the resource for example, essential oil, dried leaf, powder, extract, etc.
	Quantity: this is the volume of the commercial form of the resource and will be indicated on the permit
	Locality/source information: give the name of the closest town and the specific GPS Coordinates where the resource is located
	Traditional Knowledge: If the project was informed by traditional knowledge, select yes and the application must be accompanied by a benefit sharing agreement for the traditional knowledge
	 Applicants must only indicate species that they currently work with on the application and not species that they intend to work with. The DFFE will verify species present at the premises through a site visit and if all species indicated are not observed, the application will need to be adjusted and the process for awarding the permit will be delayed.

E: Applications for other permits	 If the applicant holds any other permits, this must be indicated in Section E and copies of the permits must be attached to the application Apart from the TOPS and CITES permits indicated here, this can also include harvesting permits from provincial authorities, etc.
	permits from provincial dutionales, etc.
F: Stakeholders	 If the business buys resource from an access provider, the details of the access provider must be included here, and the Material Transfer Agreement (Annex 11) and the Benefit Sharing Agreement (Annex 12) must be attached to the application
	If the business does not source the resource from outside of the business, but cultivate or harvest it from their own premises, no BSA or MTA is required
	If the project was informed by Traditional Knowledge, the name of the traditional knowledge holder must be indicated here, and the Benefit Sharing Agreement (Annex 12) must be attached to the application
G: Traditional Knowledge	 Include a brief description of the TK associated with the use of the resources. This information can be obtained from literature review, journals, desktop research etc. Please also provide source of information provided.
	Applicants can also visit PlantzAfrica (PlantZAfrica (sanbi.org)) - which is a SANBI website and type in the name of the species.
H: Recipients of indigenous genetic and biological resources	Here the names of clients that the resource is sold to should be indicated
	Some companies see this as confidential information in which case permission can be asked from the DFFE to only give a list of countries where the resource is sold or exported to
I: List of Annexes	Here all documents referred to in the application must be indicated and then attached. This can include, but is not limited to:
	The certified identity document of the applicant
	All permits listed
	• All MTAs and BSAs referred to
	Any relevant documents that support the information shared in the Business Plan/Project Summary section (G14)



4.4. Additional supporting documentation

Area	Guidance
Community engagement	 In cases where the access provider or the traditional knowledge holder is a community, a Community Resolution must be submitted
	The Community Resolution must be stamped and signed by the Chief
	The Community Resolution must be accompanied by minutes of the meetings with the communities
Material Transfer Agreements: Annex 11 & Benefit Sharing Agreements: Annex 12	 In the case where applications are submitted in the hard copy templates or when supporting documentation such as the MTAs and BSAs are submitted as supporting documentation on the online system, all documents must be recently dated and signed.
	 When the applicants complete the table in the BSA, it is advisable to only indicate a few options and importantly that these options are feasible for the applicant. In cases where the BAC believes that the options indicated are too ambitious, they will request a review of the BSA.
	 Where difficulty is experienced with negotiation and conclusion of MTAs and BSAs, the DFFE is able to assist and facilitate. In this case the applicant needs to confirm a meeting with the Traditional Authorities and invite the DFFE to attend the meeting to share information and motivate for the completion of the needed documentation. The DFFE must be informed of the need for support and related meetings in a timeous manner.
Provincial harvesting and collection permits	When provincial harvesting/collection or cultivation permits are required, it is good practise to get this in place prior to the applications stage and ensure that all necessary permits are submitted with the application.



4.5. The business plan/project summary

This is a very important part of the application since here the story of the business is told and will enable the DFFE and the BAC to understand the nature and activities of the business. Try to be comprehensive and succinct reducing unnecessary detail or explanations. Applicants can also refer to the template answers developed and provided by the DFFE.

Question	Explanation
Provide information on the project title	Include an overview of the company and the activities of the company here.
	The DFFE did share that it is good practise to include the intention to develop and cultivate additional resources in the business plan/project description, since then the DFFE is aware for future reference.
Provide the objectives of the project	Give information on the objectives of the company. For most this will be to produce either ingredients or finished product from indigenous biological resources and sell this to either the local or international market or both.
What are the desired outcomes of the biotrade/bioprospecting/integrated biotrade and bioprospecting project?	Here the outcomes of business activities can be summarised, for example to provide employment, to contribute to livelihoods in rural areas, to continue to run a successful business, etc.
The proposed methodology and timeframes of the activities:	Here a comprehensive overview of the activities of the company must be given, for example when do you plant, how long does the plant take to mature, when do you harvest, how does the processing work, where do you wild harvest, etc. Applicants need to describe all the activities and processes from the resource in field to the final products that they sell be this an ingredient or a final product.
List benefits for the conservation of South African biodiversity that may result from the biotrade / bioprospecting/integrated biotrade and bioprospecting	Here the applicant can share information on beneficial environmental aspects. For example if the resource is wild harvested mentioned the training of harvesters and that harvesting is done in a sustainable manner with care for the environment. In the case where the resource is cultivated refer to what environmentally friendly practises are used, how water is responsibly used, how soil health is ensured, etc.
List benefits for the South African economic development that may result from the biotrade/bioprospecting/ integrated biotrade and bioprospecting	Here economic benefits such as employment creation, poverty alleviation, bursary funds, attracting both local and foreign income can be mentioned. Businesses active in the biotrade sector also contribute to the growth of the biotrade sector in SA which can be mentioned. In the case where businesses are in rural areas, much needed employment and income is brought to these areas where economic opportunity is scarce.
List any other benefits that are in the interest of the public that may result from the biotrade /bioprospecting/integrated biotrade and bioprospecting	Here any other important information can be shared such as how the practise of the business contributes to conservation as a whole, how the business working with indigenous biological resource creates awareness of the value of these resources by bringing it to both local and export markets. If the business collaborates with academics or is part of an industry organisation working for the good of the sector, this can also be mentioned.
Provide details of the likely impact of the collection and utilization of the indigenous biological resources in its natural environment?	Most biotrade businesses conduct their activities in an environmentally responsible manner. Here it is important to not only indicate not applicable for example, but to explain why the business does not have any negative impacts and if there are some risks mention this and explain in the following point how these risks are mitigated.
What are the proposed steps to minimise or remedy the impacts listed in question 14.8?	If there are any impacts, explain here what is done to minimize the effects.
Describe how any unused/ discarded materials are or would be disposed.	This can be resource not used or byproducts from processing. Mostly this is used for fertilisation by businesses, but there are also now some businesses looking at how waste products from processing, such as hydrosol from essential oils distillation can be marketed and sold to bring income into the business.

5. Maintaining the permit

It is important to know that once the permit is issued, the applicant still has responsibilities to maintain their permitted status. Industry organisations and representatives can also assist with this and keep a record of active permits along with dates for renewal and annual reporting and remind industry members when these processes need to be implemented. Permitted biotrade businesses need to ensure that:

- They are aware of the expiry date of the permit and ensure that they start the process for renewal application at least 6 months before the expiry date
- They complete and submit the Annual Reporting Template on time every year.

The industry organisation or representative can assist the industry members by checking renewal permit applications in the same manner as set out in Section 3 and can also check that the Annual Reporting Template is completed comprehensively and with the correct information.

Apart from permitting responsibilities, the DFFE also has the responsibility to monitor that biotrade businesses are indeed compliant and that what is included in the permit application is a true reflection of the reality at business level. To ensure that this monitoring function is fulfilled, the DFFE compliance and enforcement unit may from time to time visit businesses. These visits may be announced or unannounced. During these visits the unit will check on information included in the applications and the responsibility of businesses is simply to illustrate this through physical visits to sites and supplying supporting documentation as requested.

Industry organisations can also support members here through being available and giving guidance on how to prepare for a visit or how to manage the visit once it is ongoing.



Guidance document

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Download the full document here











