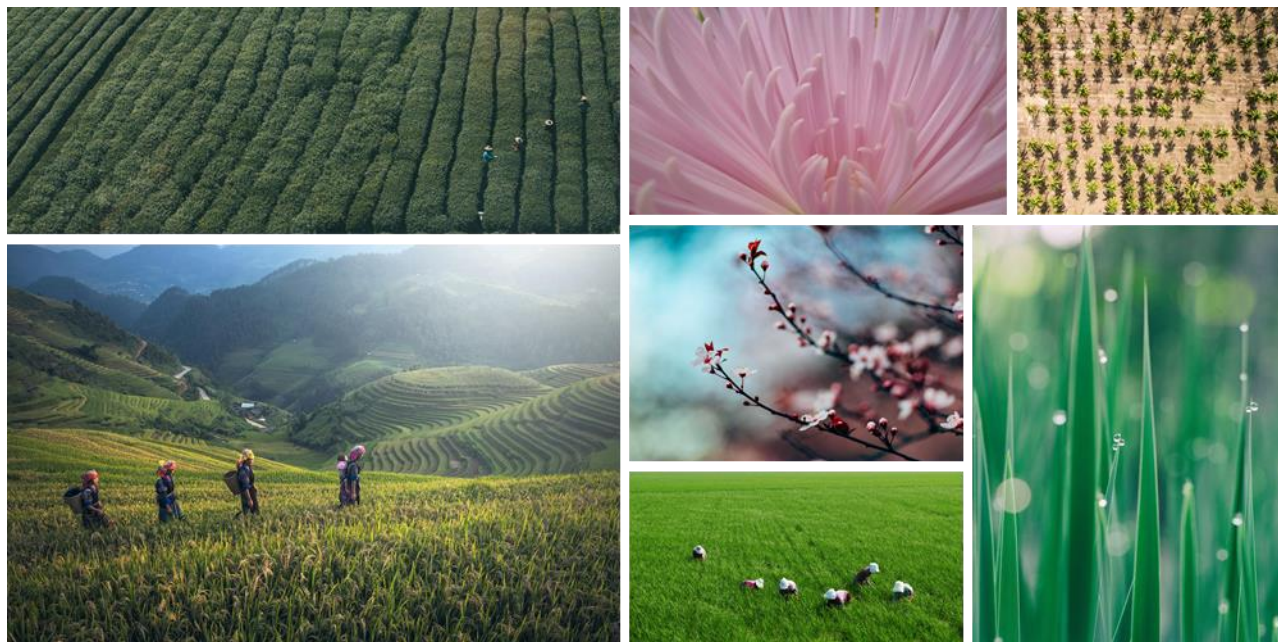




IFRA-IOFI Guidance Document  
for the Flavor and Fragrance Industry  
for dealing with the Nagoya Protocol  
and Access and Benefit Sharing (ABS) Regulations

Annex – South Africa



IFRA-IOFI Nagoya Protocol TF  
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*Note: This Chapter is still under revision by the Department of Environment, Forestry and Fisheries (DEFF). This Chapter is therefore subject to updates in the near future.*



## Contents

1	Introduction .....	7
2	National and International Legislative Background .....	7
3	General Overview of the ABS Act and Regulations .....	9
3.1	Discovery Phase Research.....	10
3.2	Bioprospecting Permit.....	10
3.3	Biotrade Permit .....	11
3.4	Research other than Bioprospecting .....	11
4	The Departmental Dynamics and Time Frames.....	11
5	Examples of Biotrade and Bioprospecting Scenarios.....	12
6	Exemptions from the permitting process in South Africa .....	16
7	Peculiarities of the permitting process in South Africa .....	16
8	Some important definitions .....	16
9	Abbreviations:.....	19
10	References .....	20



## 1 Introduction

The Annex gives an overview of the current legislative situation for Nagoya Protocol compliance in South Africa. Included are some practical considerations that illustrate the interpretation of the legislative framework by the SA authorities.

## 2 National and International Legislative Background

The following international treaties are to be considered and are having an impact on the actual legislation pertaining to Bioprospecting activities in South Africa:

### a) Convention on Biological Diversity (CBD):

South Africa ratified the Convention on Biological Diversity in 1995 – 3 years after the Rio Convention in 1992. The Convention, and later the Nagoya Protocol, rest on three pillars: the conservation of nature and of biological diversity, the sustainable utilization of biological resources and the fair and equitable sharing of benefits derived from the utilization of biological/genetic resources.

### b) Nagoya Protocol – ratified in 2014

South Africa ratified the Nagoya Protocol in 2014. The Nagoya Protocol on ABS is a supplementary agreement to the CBD and provides a legal framework for the effective implementation of the third objective of the CBD, namely the fair and equitable sharing of benefits arising from the utilization of the genetic resources.

### c) Aichi Biodiversity Targets

The CBD in 2010 adopted the Strategic Plan for Biodiversity 2011-2020 at the 10th Meeting of the Parties (COP) in Nagoya, Japan. To achieve global biodiversity conservation, the plan outlines 20 Aichi Targets.

The following national legislation has a bearing:

### a) The Constitution of the Republic of South Africa Act 108 of 1996

The SA Constitution provides the starting point from which to consider the administration of environmental law. It fundamentally defines the country's legal and administrative order and enshrines a Bill of Rights which applies to all law and is binding on all organs of state. In the context of the Constitution everyone has the right to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that prevent ecological degradation and secure ecologically sustainable use of natural resources while promoting justifiable economic and social development.

### b) National Environmental Management Act 107 of 1998 (NEMA)

NEMA provides for co-operative environmental governance by:

- establishing principles for decision making on matters affecting the environment;
- inaugurating institutions that will promote co-operative governance and procedures for co-ordinating environmental functions

The implementing agency is the Department of Environment, Forestry and Fisheries (DEFF – formerly DEA).

c) The National Environmental Management: Biodiversity Act 10 of 2004 (NEMBA)

NEMBA gives effect to the provisions of the Nagoya Protocol on a national level. It stipulates the management and conservation of biological diversity within South Africa, as well as the use of indigenous biological resources in a sustainable manner, and the fair and equitable sharing among stakeholders of benefits arising from bio-prospecting involving indigenous biological resources. It also regulates the creation and maintenance of a list of threatened or protected species (TOPS).

The implementing agency is DEFF.

d) Bioprospecting, Access and Benefit Sharing (BABS) Regulation of 2008 as amended in 2015

Chapter 6 of NEMBA deals with provisions for Bioprospecting, Access and Benefit-Sharing in South Africa. Associated with this chapter, the BABS Regulations of 2008 as amended in 2015, were gazetted. The purpose of these regulations is to prescribe

- the notification process for the discovery phase;
- the permit system applying to biotrade, bioprospecting and export of indigenous genetic and biological resources for any kind of research;
- the form, content and criteria for benefit-sharing (BSA) and material transfer agreements (MTA); and
- the administration process of the Bioprospecting Trust Fund.

NEMBA is currently under revision – specifically its Chapter 6. This revision is intended to simplify and streamline the processes for Bioprospecting, Access and Benefit Sharing substantially. The revision is hoped to be complete in 2020 with no detailed timeline set for implementation.

e) Additional legislation impacting on ABS practice

The Indigenous Knowledge Systems Bill was introduced in 2015 and has been finally signed into law on 19<sup>th</sup> August 2019 as the “Protection, Promotion, Development and Management of Indigenous Knowledge Act, 2019”.

This Act is a *sui generis* piece of legislation that endeavours to provide legislative protection for indigenous knowledge and its commercialization. It recognizes “indigenous knowledge” as a form of intellectual property.

The Act defines a new concept of “indigenous knowledge”:

- *“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;

It is important to note here, that all three conditions (a), (b) and (c) have to be met to qualify as “indigenous knowledge”.

Knowledge of a functional nature is defined as:

**“functional”**, in relation to indigenous knowledge, means knowledge that is scientific and, or technical in nature.

The Act makes provision for the establishment of the National Indigenous Knowledge Systems Office (NIKSO). A repository of “indigenous knowledge” has already been started under the guidance of the Department of Science & Innovation. NIKSO will in future adjudicate on questions of traditional and indigenous knowledge pertaining to bioprospecting and biotrade as well. It is therefore expected that additional conditions may be imposed when indigenous knowledge is being commercialized.

Indigenous knowledge is seen as a national asset that needs to be fostered, developed and protected. One of the purposes of NIKSO is in “*facilitating the redress of rights and benefits to indigenous communities which have previously been deprived of such rights and benefits;*”. The Act has therefore a strong political agenda of empowerment and transformation of South African society.

Whilst the obligations for sharing benefits based on traditional knowledge are ongoing in perpetuity, the Act limits this for indigenous knowledge for the following cases:

- (3) *In the event that the indigenous knowledge, which is the subject of the licence agreement, is:*
  - (a) *functional in nature, then any obligation on the part of the licence holder to pay a royalty expires 20 years after the date of agreement; and*
  - (b) *an indigenous cultural expression, then any obligation on the part of the user to pay a royalty expires 50 years after the date of agreement*

Regulations to the Act are yet to be published for public comment and are expected to be ready for implementation in the course of 2020.

f) Applicable Provincial ordinances pertaining to biodiversity

In addition to national legislation, the nine Provinces of South Africa have their own environmental legislations, regulations or ordinances that pertain to indigenous biological and genetic resources. Compliance to these is necessary when accessing material for biotrade, bioprospecting and research purposes. E.g. certain plants may be protected in one Province but may not be protected in other Provinces.

### 3 General Overview of the ABS Act and Regulations

All utilization of indigenous biological or genetic resources in South Africa falls under NEMBA and an application for the use of any of these needs to be made prior to accessing and using the resource. Utilization of a resource is prohibited and is punishable by law with imprisonment or penalties (up to 5 years imprisonment / ZAR 5mio penalty for first offenders and up to 10 years /

ZAR 10mio penalty for repeat offenders). So far, some cases of minor offences have become known. At this stage, DEFF is overall encouraging current and future users to become compliant rather than systematically force compliance through prosecution.

Every entity in the supply and value chain from harvester / grower / trader / processor / manufacturer needs to have some form of permit to access and utilize indigenous biological or genetic resources – this depends on the type of activity performed with or around the species. MTAs and BSAs related to access and TK are to be concluded at every level of transaction.

The current Act and Regulations recognize four distinctly different areas of utilization for which permits have to be obtained:

- Discovery Phase Research (with or without export of the resource during this phase)
- Bioprospecting (with or without export)
- Biotrade (with or without export)
- Research other than bioprospecting

An applicant can be any natural or legal person residing or being registered in South Africa. Foreign entities applying for a permit need to do so jointly with a South African natural or legal person e.g. a company, legal firm or research institution.

A specific application form for each type of permit needs to be filled in, accompanied by supporting documents (details may vary dependent on type of permit) such as:

- Application form outlining all details of the project, objectives, applicant and collaborator details, potential TK utilised and identified TK holders etc.
- Certified copy of ID document of the responsible person(s) of the applicant and collaborator(s)
- Proof of Prior Informed Consent (PIC)
- Proof of legitimacy of the benefit sharing partner in the form of e.g. a community resolution
- MTA's and BSA's for material access
- In the case of a foreign entity applying for a permit, a BSA with a relevant TK holder must be concluded.

### **3.1 Discovery Phase Research**

Discovery Phase 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 commercialization.

### **3.2 Bioprospecting Permit**

Once the research conducted during the discovery phase is at a point that sufficient certainty of commercialization has been established, a bioprospecting permit<sup>1</sup> has to be applied for.

Bioprospecting is defined as any research or development of indigenous biological or genetic resources for commercial or industrial exploitation and includes:

- the systematic search, collection or gathering of such resources;

<sup>1</sup> Bioprospecting permit application:

[https://www.environment.gov.za/sites/default/files/docs/forms/bioprospecting\\_permit\\_application.pdf](https://www.environment.gov.za/sites/default/files/docs/forms/bioprospecting_permit_application.pdf)

- the utilisation of any information regarding any traditional uses by indigenous communities for R&D purposes;
- research, development or modification of any traditional uses for commercial purposes;
- the trading in and exporting of indigenous biological resources in order to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils;
- the commercialization of the research, which includes the following activities:
  - (i) filing of an intellectual property application e.g. a patent;
  - (ii) obtaining or transferring any intellectual property rights;
  - (iii) commencing product development, conducting of market research and seeking pre-market approval for the sale of resulting products e.g. registration of a medicinal product;
  - (iv) cultivation, propagation, cloning or other means to develop and produce products.
  - (v) commercial exploitation

### **3.3 Biotrade Permit**

In cases where only trade in indigenous biological or genetic resources takes place, biotrade permit needs to be applied for. Biotrade means the buying and selling of milled, powdered, dried, sliced or extract of indigenous genetic and biological resources for further commercial exploitation.

It is important to note here that a plant extract e.g. a tincture, an essential oil, a vegetable oil or similar will fall into this category – these materials are fractions of the plant and are simply removed from the plant and not altered.

### **3.4 Research other than Bioprospecting**

Research not aimed to produce a commercially orientated outcome is exempt from some of the provisions of NEMBA. Examples for this are research in taxonomy, conservation, phylogenetics, systematics or behaviour ecology. However, a specific permit application will have to be filled in especially when research is to be conducted outside South Africa.

## **4 The Departmental Dynamics and Time Frames**

The application and any supporting documentation for any of the planned activities is compiled and handed in to the DEFF. The application goes through an initially vetting process to ensure that the application has been completed fully. The Department will engage with the applicant and request outstanding information or documents.

The complete application is – together with the relevant application fee - forwarded to the Bioprospecting Expert Committee (BEC) which consists of representatives from Nature Conservation of the 9 Provinces, SANBI as the scientific authority as well as from DEFF itself.

The BEC meets once every 3 months. The application is discussed there and referred back to DEFF either with request for further information or with the recommendation to issue the permit that has been applied for. The application makes its way through the Department and eventually

ends up with the Minister for signature. Only once the Minister has signed the permit, as well as all related BSA's and MTA's, will the agreements have legal effects.

The time frame is dependent on the completeness as well as the complexity of the application. More than one biological or genetic resource can be applied for on one application form – however, the more resources are applied for, the more documentation will have to be provided and may complicate and prolong the application and permit process. Ideally, the approval process will take not much longer than a few months but from experience it is known that this rarely happens. On average one should expect the process to take between 9 – 18 months (indicative).

Permits can be valid for up to five years. Permits should be renewed in good time before expiry to allow for the authorities to examine the renewal application.

The permit will stipulate general and specific permit conditions to be adhered to. These can range from ensuring that biological and genetic resources may only be sold to entities holding relevant biotrade and bioprospecting permits, or to request for specific contributions to conservation issues. Also, permits may be limited to the sale of the resource for specific uses only.

Bi-annual reports need to be compiled and handed in to the Department, outlining in detail the permitted usage of the resource – how much was purchased and from whom, traded, processed, sold to whom and at what monetary values.

Based on the bi-annual reports, relevant benefit sharing payments as negotiated with the benefit sharing partners are to be made into the Bioprospecting Trust Fund. This fund acts as a “post box” – payments are received by the Department, checked against the report and the benefit sharing agreements and then disbursed to the benefit sharing partner. Although cumbersome, it ensures that the correct amounts of money are paid to the rightful recipient. DEFF may, from time to time, conduct a site visit and audit the completeness and correctness of the bi-annual reports or other documentation provided. In cases of non-compliance to the permit conditions, the permit may be revoked.

## **5 Examples of Biotrade and Bioprospecting Scenarios**

Below are two examples of what types of permits are needed and who has to apply for them in specific cases. In a given supply and value chain, the type of permit application is dependent on who is applying and what the intended utilization of the biological or genetic resource will be. A permit is, however, only issued to the applicant if all collaborators in the value chain are compliant regarding their scope of activities. For example, a processor will not be issued a permit if his raw material suppliers are not compliant. The tables below illustrate two potential application scenarios for Buchu (*Agathosma* species) – one for a South African based trader and one for a foreign based processor.

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Next page:

**Table 1: South Africa ABS legal requirements – Application scenario for South African based trader of Buchu (*Agathosma* species)**

**Table 2: South Africa ABS legal requirements – Application scenario for foreign based trader of Buchu (*Agathosma* species)**

Biotrade and Bioprospecting Scenarios as discussed with DEA - August 2018														
Scenario 1		Farmer				1st level processor			Trader in SA			International Trader		
<b>Activity</b>	Buchu is bought from a farmer by a Buchu trader. The trader distills an oil from Buchu. Trader sells the oil to international company who trades with the oil	Cultivates - access to the resource				Distills oil and sells oil to trader			Sells oil to local and international clients			Sells oil to other companies locally & internationally		
<b>Permit required</b>		Biotrade	Bioprospecting	Biotrade & Bioprospecting	Other permit(s)	Biotrade	Bioprospecting	Biotrade & Bioprospecting	Biotrade	Bioprospecting	Biotrade & Bioprospecting	Biotrade	Bioprospecting	Biotrade & Bioprospecting
		n/a	n/a	n/a	Yes	Yes	n/a	n/a	Yes	n/a	n/a	Is seen as a collaborator		
<b>Documents needed</b>	Material Transfer - Access	Yes - with 1st level processor				Yes - with trader in SA			Yes - with distiller			n/a		
	Benefit Sharing - Acces	Yes - with 1st level processor				Yes - with trader in SA			Yes - with distiller			n/a		
	Benefit Sharing - TK	n/a				Yes			Yes (4)			n/a		
<b>Principal Applicant</b>		n/a				n/a			Yes (3)			n/a		
<b>Validity period of permit</b>		Permit specific				1 - 5 Years			1 - 5 Years			n/a		
<b>Notes</b>														
(1) Other permits may be needed when clearing virgin lands for cultivation, harvesting permits from Nature Conservation authorities, Flora Grower and Seller Permit (Western Cape), permission from land owners, etc.														
(2) Distillation is seen as Biotrade as the product is not ready for final consumption														
(3) International trader is seen as collaborator / agent of the local applicant - needs to be listed as such with relevant documentation (full details agent, certified copy of passport etc.														
(4) With relevant Traditional Knowledge (TK) holder														

Biotrade and Bioprospecting Scenarios as discussed with DEA - August 2018																				
Scenario 2		Community		Farmer			1st level processor			Trader in SA		International Trader		International Brand Owner						
<b>Activity</b>	Buchu is bought from a farmer by a Buchu Trader. The Trader distills an oil from Buchu. Trader sells the oil to international company who trades with the oil	Harvests from the wild access to the resource		Cultivates - access to the resource			Distills oil and sells oil to trader			Sells oil to local and international clients		Sells oil to other companies locally & internationally		Compounds Buchu oil or oil blend into final consumer product						
<b>Permit required</b>		Biotrade	Bioprospecting	Biotrade & Bioprospecting	Other permit(s)	Biotrade	Bioprospecting	Biotrade & Bioprospecting	Other permit(s)	Biotrade	Bioprospecting	Biotrade & Bioprospecting	Biotrade	Bioprospecting	Biotrade & Bioprospecting					
					Yes (1)				Yes (1)	Yes (2)			Yes (2)	n/a	n/a	n/a	n/a	n/a	n/a	Yes (2)
<b>Documents needed</b>	Material Transfer - Access	Yes - with 1st level processor		Yes - with 1st level processor			Yes - with resource provider			Yes - with trader		Yes - with trader		Yes with trader						
	Benefit Sharing - Acces	Yes - with 1st level processor		Yes - with 1st level processor			Yes - with resource provider			Yes - with processor (3)		Yes - with trader (4)		Yes - with trader (4)						
	Benefit Sharing - TK	n/a		n/a			n/a			n/a		n/a		Yes - with TK holder (6)						
<b>Principal Applicant</b>		n/a		n/a			n/a			n/a		n/a		Yes (3, 6)						
<b>Validity period of permit</b>		1 to 5 Years		1 to 5 Years			1 to 5 Years			1 to 5 Years		n/a Years		5 Years						
<b>Notes</b>																				
(1) Other permits may be needed when clearing virgin lands for cultivation, harvesting permits from Nature Conservation authorities, Flora Grower and Seller Permit (Western Cape), permission from land owners, etc.																				
(2) The Distillation is seen as Biotrade (as it is not a final consumer good). Incorporation into a final consumer product triggers Bioprospecting application																				
(3) The International Processor includes the international trader as well as the SA trader / processor as agent / collaborator. The permit is applied for and issued to the international applicant jointly with a local SA company e.g. the trader.																				
(4) The SA processor / trader lists the international trader as collaborator / agent																				
(5) No further engagement at this stage (although one is thinking about reaching to the international trade to include them in ABS - this could just be wishful thinking as the foreign entity is outside the reach of SA law)																				
(6) With relevant Traditional Knowledge (TK) holder																				



The above tables are somewhat simplified in that they reflect only “one layer” of the reality. A processor may have 20 – 30 or even more different suppliers – with each one a Material Transfer and a Benefit Sharing Agreement has to be concluded. Due to various circumstances, suppliers change – some may fall away or supply another company, others may become part of the supply chain. Each time a change happens, the processor needs to conclude an MTA and BSA and send them off for approval by the Minister and, strictly speaking, the new supplier can only become part of the supply chain once this approval has been received. The same would apply for each customer – both local and international. For example, a Buchu processor with e.g. 20 suppliers and 10 clients may thus have to conclude and administer 30 MTA’s and 30 BSA’s for access to the material. The agreements need to be renegotiated every time the permit has to be renewed. Altogether this represents an immense transactional burden with substantial associated cost in time and money.

For the Flavour and Fragrance industry, the following comments are important:

- In defining BIOPROSPECTING, the National Environmental Management Biodiversity Act (NEMBA) states it being, amongst others, “research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation; and the trading in and exporting of indigenous biological resources in order to develop and produce products, such as drugs, industrial enzymes, food flavors, fragrances, cosmetics, emulsions, oleoresins, colors, extracts and essential oils”.
- A BIOPROSPECTING permit is required for “the trading in and exporting of indigenous biological resources (IBR) in order to develop and produce products, such as drugs, industrial enzymes, food flavors, fragrances, cosmetics, emulsifiers, oleoresins, colors, extracts and essential oils”. Therefore, in the sense of Flavorings and Fragrance Compounds, it is reasonably clear that mainly the BIOTRADE and BIOPROSPECTING permit comes into question for our industry.
- "BIOTRADE" means the buying and selling of milled, powdered, dried, sliced or extract of indigenous genetic and biological resources for further commercial exploitation.

Taking Buchu as an example, the following activities would notably fall into the category of Biotrade:

- Initial processing of Buchu e.g. drying, milling etc. and the sale/trade of these product.
- Extraction of the essential oil and the sale / trade with the essential oil.
- Fractionation of the essential oil and the sale / trade of the fractions.
- Manufacturing a Buchu tincture or other type extract for medicinal or cosmetic purposes.

The following type of activities would notably fall into the category of Bioprospecting:

- Development work on any of the above whereby the nature of the oil or fraction thereof is altered, e.g. a new chemical entity is created from the oil or fractions.
- Incorporating the oil, fractions thereof or blends of Buchu oil with other ingredients to create flavorings and fragrance compounds.
- Creating finished consumer goods incorporating the oil, fractions thereof or blends of Buchu oil with other oils, tinctures or other extracts etc. – e.g. an herbal medicine to assist with urinary tract infections or a Buchu cosmetic cream.

The critical change from biotrade to bioprospecting is triggered by the creation of a flavoring, fragrance compound or a finished consumer goods. Where a foreign company, manufacturing consumer products, sources oils directly in South Africa, it would need to apply for a bioprospecting permit. Where a foreign company, manufacturing consumer goods, purchases the oil from a biotrader outside South Africa, a bioprospecting permit should be applied for as well—however, this is very difficult to monitor and enforce. All biotradors, whether located inside or outside South Africa must ensure that the Buchu leaves, oil or fractions thereof are obtained from a compliant source.

In the Flavour and Fragrance industry, the following activities would notably fall under the Discovery Phase Permit:

- Research and development work on the Buchu leaves, oil or fractions that aims to create new products/compounds/chemically altered products. Research with a fraction of Buchu oil e.g. to be used as a preservative, anti-foaming agent, additive in other chemical processes etc. is in scope for a Discovery Phase Permit application.

The terms “application” in NEMBA and “use” in Article 17 4(i) of the Nagoya Protocol have not been further defined in the South Africa legislation. This is the root of a very unclear situation. It seems, for instance, that the EU definition of “utilization” is conducting research and development, which is not the same as in South Africa, where “use” is meant more in the sense of “usage” as in “the action of using something or the fact of being used”<sup>2</sup>.

In order to create a fragrance compound or flavoring containing Buchu, the Bioprospector must ensure his own compliance, as well as the compliance of the oil he is using. When offering this blend to a company producing a consumer product (brand owner level), there should be proof of compliance (e.g. due diligence or a permit) and ideally, the brand owner of the consumer goods should apply for a bioprospecting permit. For many practical reasons this is currently difficult to monitor and implement and therefore relies on voluntary compliance of the consumer goods brand owner in the spirit of the Nagoya Protocol.

What is still unclear is whether the application for a bioprospecting permit by an F&F company would require a specific use to be indicated (for example: Blackcurrant flavoring) or whether the generic “Flavorings” or “Fragrance Compounds” would be acceptable. If the former, a number of other questions arise, such as how to describe a specific fragrance compound, what latitude would be tolerated and so on.

The next step in the value chain remains unclear. The manufacturer of the finished consumer goods would probably need a bioprospecting permit and the supplier of the flavoring or fragrance compound a biotrade permit. These permits are required at the time of submitting samples for trials or only when it is clear that commercial quantities are to be supplied. In the latter case, this could delay the launch of the consumer product for several months.

Experience shows that the application and interpretation of NEMBA and its regulations does evolve over time. No one supply chain is the same as another, no traditional knowledge is the same as another, a spread of traditional knowledge holders will have their individual way of approaching the benefit sharing negotiations, etc. – so, there will always be a measure of variation

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<sup>2</sup> Definition from <https://www.lexico.com/en/definition/usage>

how the Act and regulations would be implemented in an individual case, be it on single applicant or industry sector wide level.

## **6 Exemptions from the permitting process in South Africa**

- Human genetic resources are exempt from bioprospecting regulations
- Horticultural crops such as cut flowers or pot plants
- The collection and use of indigenous resources for personal and subsistence use – this also applies to a traditional healer who may harvest medicinal plants for his traditional healing practice.
- Any exotic animals, plants or other organisms, other than exotic animals, plants or other Organisms referred to in paragraph (a)(iii); and
- Indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture.

## **7 Peculiarities of the permitting process in South Africa**

- The implementation of the Nagoya Protocol has a very strong political component. It is intended to address the wrongs of the past and the present and are hoped to be a tool for poverty alleviation as well as to bring economic development and inclusion to otherwise marginalized rural people.
- The Nagoya Protocol typically excludes food plants from the provisions so as not to endanger local food security issues. In South Africa, this is not the case – as can be seen in the recently concluded bioprospecting negotiations around Rooibos Tea.
- Usually, the provisions of a national legislation start from a specific date of entry into force, after ratification of the legal framework in the respective country. e.g. in the EU, the relevant guidelines apply to genetic resources used by EU-users accessed only on or after 12 October 2014. In South Africa, there is no cut-off date – all biological or genetic resources fall under NEMBA regardless of when they were accessed or utilized for the first time.
- The ownership of traditional knowledge is often not well defined in the South Africa Legislation. Different interpretations do exist amongst traditional groupings that claim to be the custodians and therefore the rightful owner of traditional knowledge.
- Every time that an indigenous biological or genetic resource changes hands and ownership, an MTA and BSA will have to be concluded. This leads to a very cumbersome and complex web of documentation and agreements that have to be carefully designed and maintained during the duration of the validity period of the permit.

## **8 Some important definitions**

In line with the general disclaimer (page 3), the definitions mentioned below are based on the South Africa legislation but may have been summarized or shortened for the reading easiness.

**Benefit** means any benefit arising from bioprospecting or biotrade and includes both monetary and non-monetary returns



**Biotope** means the buying and selling of milled, powdered, dried, sliced or extract of indigenous genetic and biological resources for further commercial exploitation.

**Bioprospecting**<sup>3</sup>, in relating to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes:

- the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application;
- the utilization for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities;
- research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation; or
- the trading in and exporting of indigenous biological resources in order to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils.

**Commercial Exploitation**<sup>4</sup> means the engaging in any bioprospecting activity with the intention of making a profit.

**Commercialisation**<sup>5</sup>, in relation to indigenous biological resources, includes the following activities:

- the filing of any complete intellectual property application, whether in South Africa or elsewhere;
- obtaining or transferring any intellectual property rights;
- commencing product development, including the conducting of market research and seeking pre-market approval for the sale of resulting products;
- The multiplication of indigenous biological resources through cultivation, propagation, cloning or other means to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils;
- trading in and exporting of indigenous biological resources to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils;
- commercial exploitation.

**Commercialisation phase of bioprospecting**<sup>6</sup> 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.

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<sup>3</sup> The definition of Bioprospecting was amended by section 1(b) of Act 14 of 2013

<sup>4</sup> Definition of "commercial exploitation" was inserted by section 1(c) of Act 14 of 2013.

<sup>5</sup> Definition of "commercialization" inserted by section 29 of Act 14 of 2009 and amended by section 1(d) of Act 14 of 2013.

<sup>6</sup> Definition of "commercialisation phase of bioprospecting" inserted by section 29 of Act 14 of 2009.

**Derivative**, in relation to an animal, plant or other organism, means any part, tissue or extract of an animal, plant or other organism, whether fresh, preserved or processed, and includes any genetic material or chemical compound derived from such part, tissue or extract.

**Discovery phase of bioprospecting**<sup>7</sup> 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.

**Genetic material** means any material of animal, plant, microbial or other biological origin containing functional units of heredity.

**Genetic resource** includes any genetic material or the genetic potential, characteristics or information of any species.

**Indigenous biological resource:**

- when used in relation to bioprospecting, means any indigenous biological resource as defined in section 80(2); or
- when used in relation to any other matter, means any resource consisting of-
  - any living or dead animal, plant or other organism of an indigenous species;
  - any derivative of such animal, plant or other organism; or
  - any genetic material of such animal, plant or other organism.

Section 80(2) falls under Chapter 6 of NEMBA. In this Chapter, **Indigenous biological resource:**

(a) includes:

- (i) Any indigenous biological resources as defined in paragraph (b) of the definition of "indigenous biological resource" in section 1, whether gathered from the wild or accessed from any other source, including any animals, plants or other organisms of an indigenous species cultivated, bred or kept in captivity or cultivated or altered in any way by means of biotechnology;
- (ii) Any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms referred to in subparagraph (i); and
- (iii) Any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the application of biotechnology, have been altered with any genetic material or chemical compound from any indigenous species or any animals, plants or other organisms referred to in subparagraph (i) or (ii); but

(b) excludes:

- (i) Genetic material of human origin;
- (ii) Any exotic animals, plants or other organisms, other than exotic animals, plants or other Organisms referred to in paragraph (a)(iii); and
- (iii) Indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture.

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<sup>7</sup> Definition of "discovery phase of bioprospecting" inserted by section 29 of Act 14 of 2009.

**Indigenous species** means a species that occurs, or has historically occurred, naturally in a free state in nature within the borders of the South African Republic but excludes a species that has been introduced in the Republic as a result of human activity.

**Local community** means any community of people living or having rights or interests in a distinct geographical area.

**Traditional use or 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.

**Specimen** means:

- any living or dead animal, plant or other organism;
- a seed, egg, gamete or propagule or part of an animal, plant or other organism capable of propagation or reproduction or in any way transferring genetic traits;
- any derivative of any animal, plant or other organism; or
- any goods which:
  - contain a derivative of an animal, plant or other organism or
  - from an accompanying document, from the packaging or mark or label, or from any other indications, appear to be or to contain a derivative of an animal, plant or other organism.

**Stakeholder** means:

- a person, an organ of state or a community providing access to the indigenous biological resources or
- an indigenous community:
  - whose traditional uses of the indigenous biological resources relates to, have initiated, will contribute to or form part of the proposed bioprospecting; or
  - whose knowledge of or discoveries about the indigenous biological resources are to be used for bioprospecting.

## 9 Abbreviations:

ABS	Access and Benefit Sharing
BABS	Bioprospecting Access and Benefit Sharing
BMP-S	Biodiversity Management Plan for Species
BSA	Benefit Sharing Agreement
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species
DAFF	Department of Agriculture Forest and Fisheries (since May 2019 renamed to Department of Agriculture – DA)
DEA	Department of Environmental Affairs
DEFF	Department of Environment, Forest and Fisheries (since May 2019, formerly DEA)
IK	Indigenous Knowledge
IP	Intellectual Property

IUCN	International Union for Conservation of Nature
MTA	Material Transfer Agreement
NEMA	National Environmental Management Act
NEMBA	National Environmental Management Biodiversity Act
NEMPAA	National Environmental Management Protected Areas Act
NIKSO	National Indigenous Knowledge Systems Office
SANBI	South African National Biodiversity Institute
TK	Traditional Knowledge
TOPS	Threatened Or Protected Species

## 10 References

References can be searched at:

<http://www.gpwonline.co.za/Gazettes/Pages/Government-Gazette.aspx>

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Government Gazette No. 26436, Vol. 467 - 7 June 2004: National Environmental Management: Biodiversity Act 2004 (Act No. 10 of 2004)<sup>8</sup>

Government Gazette No. 30739, Vol. 512 – 8 Feb 2008: National Environmental Management: Biodiversity Act (10/2004): Commencement of Bio-Prospecting, Access and Benefit-Sharing Regulations, 2008; Regulations on Bio-Prospecting, Access and Benefit-Sharing<sup>9</sup>

Government Gazette No 38600, Vol. 597 - 31 March 2015: National Environmental Management: Biodiversity Act 2004 (Act No. 10 of 2004) Threatened of Protected Species Regulations – published for public comment <sup>10</sup>

Government Gazette No. 38809, Vol. 599 – 19 May 2015: National Environmental Management: Biodiversity Act (10/2004): Amendments to the regulations on Bio-prospecting, access and benefit-sharing<sup>11</sup>

Government Gazette No. 1082 - 19 August 2019: Act No. 6 of 2019: Protection, Promotion, Development and Management of Indigenous Knowledge Act, 2019<sup>12</sup>

Draft Biodiversity Management Plan for Aloe Ferox, DEFF internal document – June 2019<sup>13</sup>

### Additional documentation:

South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators (Department of Environmental Affairs, 2012, ISBN 978 0 621 40885 0)<sup>14</sup>

<sup>8</sup> [https://www.environment.gov.za/sites/default/files/legislations/nema\\_amendment\\_act10.pdf](https://www.environment.gov.za/sites/default/files/legislations/nema_amendment_act10.pdf)

<sup>9</sup> [https://www.environment.gov.za/sites/default/files/legislations/nemba\\_regulations\\_g30739rg8831gon138\\_0.pdf](https://www.environment.gov.za/sites/default/files/legislations/nemba_regulations_g30739rg8831gon138_0.pdf)

<sup>10</sup> [https://www.environment.gov.za/sites/default/files/legislations/nemba10of2004\\_topsregulations\\_0.pdf](https://www.environment.gov.za/sites/default/files/legislations/nemba10of2004_topsregulations_0.pdf)

<sup>11</sup> <https://cer.org.za/wp-content/uploads/2010/05/Amendments-to-Regulations-on-Bioprospecting-access-and-benefit-sharing.pdf>

<sup>12</sup> [https://www.gov.za/sites/default/files/gcis\\_document/201908/4264719-8act6of2019protectpromodevelopmanagementindigenousknowledgeact.pdf](https://www.gov.za/sites/default/files/gcis_document/201908/4264719-8act6of2019protectpromodevelopmanagementindigenousknowledgeact.pdf)

<sup>13</sup> <https://cer.org.za/wp-content/uploads/2004/09/Draft-NDF-Aloe-ferox.pdf>

<sup>14</sup> [https://www.environment.gov.za/sites/default/files/legislations/bioprospecting\\_regulatory\\_framework\\_guideline.pdf](https://www.environment.gov.za/sites/default/files/legislations/bioprospecting_regulatory_framework_guideline.pdf)





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