The Minister of Environmental Affairs and Tourism has, under section 97(1)(d), (e), (f), (g) and (h) of the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004), made the Regulations in the Schedule.

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INTERPRETATION AND PURPOSE OF REGULATIONS

1. Definitions

In these Regulations, a word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context otherwise indicates -
"the Act" means the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004).

"any other kind of research" means research other than bioprospecting and -

(a) includes the systematic collection, study or investigation of indigenous biological resources, conducted under the auspices of a bona fide research institute or organisation to generate scientific knowledge; but

(b) excludes incidental surveys and searches;

"applicant" means a person who has submitted, a permit application;

"benefit-sharing agreement" means an agreement in the form of Annexure 8, concluded between an applicant for a permit and a stakeholder, which provides for sharing by the stakeholder in any future benefits that may be derived from the bioprospecting to which the application relates;

"bioprospecting permit" means a permit, issued in terms of section 88 of the Act, to engage in the discovery phase and/or commercialisation phase of a bioprospecting project;

"Bioprospecting Trust Fund" means the Fund established by section 85(1) of the Act:

"commercialisation" includes the following activities in relation to indigenous biological resources-

(a) the filing of any complete intellectual property application, whether in South Africa or elsewhere:

(b) obtaining or transferring any intellectual property rights or other rights;

(c) commencing clinical trials and product development, including the conducting of market research and seeking pre-market approval for the sale of resulting products; or

(d) 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, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts;

"commercialisation phase 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;
"confidential information" means information which, if disclosed, may be detrimental to the commercial or financial interests of a party to a benefit-sharing agreement, and -

(a) includes -

(i) information about research being or to be carried out including details of species to be collected and areas in which specified species are to be collected;

(ii) financial commercial, scientific or technical information including trade secrets;

(iii) indigenous knowledge if the disclosure of that knowledge may be detrimental to the relevant indigenous community; but

(a) excludes information -

(i) that has already been disclosed through publication in a scientific journal;

(ii) if the parties consent to its disclosure;

"discovery phase 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 not sufficiently clear or known to begin the process of commercialisation;

"export permit for research other than bioprospecting" means a permit, issued in terms of section 88 of the Act, for exporting from the Republic any indigenous biological resources for the purposes of research other than bioprospecting;

"indigenous community" means any community of people living or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure and-

(a) whose traditional uses of the indigenous biological resources to which an application for a permit relates, have initiated or will contribute to or form part of the proposed bioprospecting; or

(b) whose knowledge of or discoveries about the indigenous biological resources to which an application for a permit relates are to be used for the proposed bioprospecting;

"indigenous use or knowledge" includes knowledge of, discoveries about or the traditional use of indigenous biological resources, if that knowledge, discovery or use has initiated or will contribute to or form part of a proposed bio-prospecting or research project to which an application for a permit relates;
"integrated export and bioprospecting permit" means a permit, issued in terms of section 88 of the Act to export indigenous biological resources for the purpose of bioprospecting;

"material transfer agreement" means an agreement in the form of Annexure 7 between an applicant for a permit and a person, including any organ of state or community, providing or giving access to the indigenous biological resources to which the application relates;

"NEMA" means the National Environmental Management Act, 1998 (Act No. 107 of 1998);

"permit" means a permit issued in terms of Chapter 7, being a bioprospecting permit; an integrated export and bioprospecting permit; or an export permit for research other than bioprospecting;

"traditional use or knowledge" refers to the customary utilisation or knowledge of indigenous biological resources by an indigenous community, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised by them, and includes discoveries about the relevant indigenous biological resources by that community.

2. Purpose of Regulations

The purpose of these Regulations is to -

(a) further regulate the permit system set out in Chapter 7 of the Act insofar as that system applies to bioprospecting involving any indigenous biological resources or export from the Republic of any indigenous biological resources for the purpose of bioprospecting or any other kind of research and;

(b) set out the contents of, the requirements and criteria for benefit-sharing and material transfer agreements.

3. Application of Regulations

(1) These regulations govern -

(a) the discovery phase and/or commercialisation phase of a bioprospecting project;

(b) the export from the Republic of any indigenous biological resources for the purpose of bioprospecting; and

(c) the export from the Republic of any indigenous biological resources for any other kind of research.
CHAPTER 1
CONDITIONS UNDER WHICH BIOPROSPECTING AND RESEARCH OTHER THAN BIOPROSPECTING MAY BE CARRIED OUT

4. Bioprospecting

(1) Discovery phase and/or commercialisation phase of a bioprospecting project may only be carried out with a bioprospecting permit issued by the Minister.

(2) If the applicant for a bioprospecting permit intends exporting the indigenous biological resources to which the application relates, the applicant must apply to the Minister for an integrated export and bioprospecting permit.

(3) The Minister may only issue a bioprospecting permit or an integrated export and bioprospecting permit after complying with the requirements of Regulations 8(1) and 9(1).

5. Research other than bioprospecting

(1) Indigenous biological resources may only be exported for a research purpose other than bioprospecting with an export permit issued by the issuing authority identified in Regulation 6.

(2) An export permit for research other than bioprospecting may be issued as part of an integrated permit provided the issuing authority complies with section 92 of the Act.

(3) Before issuing an export permit for research other than bioprospecting, the issuing authority must comply with Regulations 9(1) and 13(1).

CHAPTER 2
PERMIT SYSTEM FOR BIOPROSPECTING AND EXPORTING INDIGENOUS BIOLOGICAL RESOURCES

Part I: issuing authorities

6. Designation of issuing authorities

(1) The Minister is the issuing authority for -

(a) bioprospecting permits; and

(b) integrated export and bioprospecting permits, if the indigenous biological resources are being exported for the purposes of bioprospecting.
(2) The MEC is designated as the issuing authority for export permits, if the indigenous biological resources are being exported for research purposes other than bioprospecting, and the indigenous biological resources to be exported are collected, gathered or curated in that province.

(3) Delegation of powers and duties by an issuing authority can only be done in accordance with sections 42 and 42A of the NEMA.

7. **Powers and duties of issuing authorities**

(1) An issuing authority must process all applications within a reasonable time.

(2) Before issuing a permit in terms of these Regulations, an issuing authority must satisfy itself that -

- (a) the impact of the relevant activity on the indigenous biological resources will be negligible or will be minimised and remedied; and

- (b) the relevant activity will not deplete an indigenous biological resource beyond a level where its integrity is jeopardised.

(5) On receipt of an application for a permit an issuing authority -

- (a) must consider the application;

- (b) may require the applicant or any stakeholders to furnish additional information;

- (c) may require an applicant to undertake a risk assessment in accordance with section 89 of the Act or in terms of any other regulations promulgated in terms of the Act.

(3) After having reached a decision on an application for a permit an issuing authority must -

- (a) notify the applicant of the decision in writing within 15 working days after making the decision;

- (b) if the application was approved, issue the permit, amend the permit, or renew the permit, as the case may be, within 15 working days after making the decision;

- (c) if the application was refused -

  - (i) notify the applicant of the decision in writing within 15 working days after making the decision;

  - (ii) give reasons for the refusal; and
(iii) inform the applicant of the applicant’s right to appeal against the decision in terms of section 94 of the Act and Regulation 16.

(4) An issuing authority must monitor all permit holders to ensure compliance with permit conditions.

8. **Conditions subject to which issuing authorities may issue permits**

(1) The Minister may only issue a bioprospecting permit or an integrated export and bioprospecting permit, if the Minister is satisfied that -

(a) the relevant stakeholders have been identified in accordance with the principles set out in section 82 of the Act;

(b) there has been disclosure of relevant information to all the stakeholders that have been identified;

(c) the applicant has obtained the prior consent of any person, including any organ of state or community providing or giving access to the indigenous biological resources to which the application relates, and material transfer agreements and benefit-sharing agreements have been entered into with such stakeholders;

(d) the applicant has obtained the prior consent of affected indigenous communities, and benefit-sharing agreements have been entered into with such communities.

(2) In order to satisfy himself or herself that the requirements of the Act and these Regulations have been met, the Minister may require an applicant for a bioprospecting permit or an integrated export and bioprospecting permit to -

(a) show what steps have been taken to identify stakeholders;

(b) take further steps to identify stakeholders;

(c) provide evidence that relevant information relating to the bioprospecting has been disclosed to the identified stakeholders;

(d) provide evidence that the prior consent of identified stakeholders has been obtained.

**Part 2: Application for permits**

9. **Applicant**
(1) A permit in terms of the Act may only be issued to -

(a) a juristic person registered in terms of South African law;

(b) a natural person, who is a South African citizen or a permanent resident of South Africa;

(c) a juristic person that is not registered in terms of South African law or a natural person who is not a South African citizen or a permanent resident of South Africa, if that juristic person or foreign national applies jointly with a juristic or natural person referred to in paragraphs (a) or (b) above.

(2) An applicant for a permit must -

(a) disclose if, in respect of the indigenous biological resources to which the application relates -

(i) any other application for a permit in terms of the Act or in terms of any other legislation has been submitted to any authority either previously or simultaneously with the current application; and

(ii) whether that application was refused or granted or is still pending;

(b) if the bioprospecting was preceded by research other than bioprospecting in relation to the indigenous biological resources to which the application relates, disclose the nature of the research and the activities resulting in the application for a bioprospecting permit.

10. Application procedure

(1) An application for a bioprospecting permit must be submitted to the Minister and must -

(a) be in the form of Part 1 of Annexure 2 to these Regulations;

(b) contain sufficient information to enable the Minister to make the relevant assessment.

(2) An application for an integrated export and bioprospecting permit must be submitted to the Minister and must -

(a) be in the form of Parts 1 and 2 of Annexure 2 to these Regulations;

(b) contain sufficient information to enable the Minister to make the relevant assessment.
If material transfer agreements or benefit-sharing agreements are required by the Act, an applicant for a bioprospecting permit or an integrated export and bioprospecting permit must attach to the application for such permit -

(a) signed material transfer agreements or benefit-sharing agreements if such agreements have been concluded; or

(b) if it has not been possible to conclude such agreements, a request for the intervention of the Minister for the purposes of negotiating such agreements, in accordance with section 82(4)(b) of the Act.

An application for an export permit for research purposes other than bioprospecting must be submitted to the MEC identified in regulation 6(2) and must -

(a) be in the form of Annexure 3 to these Regulations;

(b) contain sufficient information to enable the MEC to make the relevant assessment.

**Part 3: Issuing of permits and content of permits**

11. **Bioprospecting permits**

(1) A bioprospecting permit may only be issued if –

(a) the Minister has approved any material transfer agreements or benefit-sharing agreements that are required by the Act and have been submitted to the Minister; and

(b) the non-refundable fee specified in Annexure 1 has been paid.

(2) A bioprospecting permit must -

(a) be in the form of Annexure 4 to these Regulations;

(b) specify the period for which the permit is valid;

(c) specify the indigenous biological resources involved;

(d) specify the quantity of indigenous biological resources involved;

(e) specify the source of the indigenous biological resources;
(f) be issued subject to conditions as determined by the Minister, which conditions must include that -

(i) all money due to stakeholders in terms of a benefit-sharing agreement must be paid into the Bioprospecting Trust Fund, as required by section 85(1) of the Act;

(ii) the permit-holder must, on an annual basis, submit a status report to the Minister in a format determined by the Minister;

(iii) the permit-holder will be liable for the costs of mitigating or remedying the impact of the bioprospecting on the environment, in accordance with section 28 of the NEMA; and

(iv) the indigenous biological resources to which a permit relates may not be sold, donated or transferred to a third party without the written consent of the Minister.

12. Integrated export and bioprospecting permits

(1) An integrated export and bioprospecting permit may only be issued if the Minister is satisfied that the export of indigenous biological resources for bioprospecting will be for a purpose that is in the public interest, including -

(a) the conservation of biodiversity in South Africa;

(b) the economic development of South Africa; or

(c) enhancing the scientific knowledge and technical capacity of South African people and institutions.

(2) An integrated export and bioprospecting permit must -

(a) be in the form of Annexure 5 to these Regulations;

(b) specify the period for which the permit is valid;

(c) specify the indigenous biological resources involved;

(d) specify the quantity of indigenous biological resources involved;

(e) specify the source of the indigenous biological resources;
(f) be issued subject to conditions as determined by the Minister, which conditions must include that -

(i) all money due to stakeholders in terms of a benefit-sharing agreement must be paid into the Bioprospecting Trust Fund, as required by section 85(1) of the Act;

(ii) the permit-holder must, on an annual basis, submit a status report to the Minister in a format determined by the Minister;

(iii) the permit-holder will be liable for the costs of mitigating or remedying the impact of the bioprospecting on the environment, in accordance with section 28 of the NEMA; and

(iv) the indigenous biological resources to which a permit relates may not be sold, donated or transferred to a third party without the written consent of the Minister.

13. **Export permit for research other than bioprospecting**

(1) An export permit for research other than bioprospecting may only be issued if the issuing authority identified in Regulation 6 is satisfied that the export of the relevant indigenous biological resources will be for a purpose that is in the public interest, including -

(a) the conservation of biodiversity in South Africa;

(b) the economic development of South Africa; or

(c) enhancing the scientific knowledge and technical capacity of South African people and institutions.

(2) An export permit for the export of indigenous biological resources for research purposes other than bioprospecting -

(a) must be in the form of Annexure 6 to these Regulations;

(b) must indicate the period for which it is valid;

(c) must specify the indigenous biological resources involved;

(d) must specify the quantity of indigenous biological resources involved;

(e) must specify the source of the indigenous biological resources; and
must be issued subject to the following conditions -

(i) the indigenous biological resources to which the permit relates, may only be used for non-commercial research purposes as specified on the permit;

(ii) the indigenous biological resources to which the permit relates may not be used for bioprospecting purposes;

(iii) the permit-holder will be liable for the costs of mitigating or remedying the impact of the export on the environment, in accordance with section 28 of the NEMA;

(iv) the indigenous biological resources to which the permit relates may not be sold, donated or transferred to a third party without the written consent of the issuing authority, which consent will not be given if the third party intends using the resources for bioprospecting purposes; and

(v) the permit-holder must, on an annual basis or on timeframes as determined by the issuing authority, submit a status report to the issuing authority in a format determined by the issuing authority.

Part 4: Appeals

14. Decisions that are subject to appeal

(1) An applicant may appeal, in terms of section 94 of the Act, any decision to -

(a) refuse a permit;

(b) impose permit conditions that are in addition to mandatory conditions required to be imposed in terms of these Regulations;

(c) cancel a permit.

15. Procedure on appeal

(1) An appeal must be lodged with the Minister within 30 days of the applicant receiving notification of the decision being appealed against.
Stakeholders who have an interest in the appeal must be provided with a copy of the appeal and must be notified that they have 15 days from date of notification to lodge submissions in relation to the appeal with the Minister.

An appeal must -

(a) set out the grounds on which the decision is being appealed;

(b) identify any stakeholders who have an interest in the appeal and provide proof that a copy of the appeal has been served on all stakeholders; and

(c) be accompanied by the non-refundable fee set out in Annexure 1.

CHAPTER 3
MATERIAL TRANSFER AGREEMENTS, BENEFIT-SHARING AGREEMENTS AND THE ADMINISTRATION OF THE BIOPROSPECTING TRUST FUND

Part 1: Agreements

16. Material transfer agreements

(1) Parties to a material transfer agreement are the applicant and the stakeholder as described in paragraphs 82(1)(a) and (b) of the Act who provides or gives access to the indigenous biological resources to which an application relates.

(2) The Minister must approve all material transfer agreements or any amendment to such agreements, in accordance with section 84(2) of the Act.

(3) A material transfer agreement must be in the form of Annexure 7 and must contain the information specified in section 84(l)(b) of the Act.

17. Benefit-sharing agreements

(1) Parties to a benefit-sharing agreement are the applicant and the stakeholders referred to in section 82(1)(a) and (b) of the Act.

(2) A benefit-sharing agreement must be in the form of Annexure 8 and must comply with subsections 83(1) and (2) of the Act;

(3) Before approving a benefit-sharing agreement or an amendment to such agreement, the Minister -

(a) must be satisfied that the agreement is fair and equitable to all parties;
may consult any person competent to provide technical advice on the agreement; and

(c) may invite public comment on the agreement provided that no confidential information is made public.

(4) The Minister may refuse to approve a benefit-sharing agreement unless such agreement makes some provision for -

(a) enhancing the scientific knowledge and technical capacity of persons, organs of state or indigenous communities to conserve, use and develop indigenous biological resources; or

(b) any other activity that promotes the conservation, sustainable use and development of the relevant indigenous biological resources.

(5) Permit-holders must lodge a copy of all benefit-sharing agreements with the Director-General, within one month of an agreement being concluded or within one month of any amendments to such agreement being concluded.

18. Duties of Permit-holder

(1) The holder of a bioprospecting permit or an integrated export and bioprospecting permit must -

(a) notify the Director-General when money due to stakeholders as specified in the benefit-sharing agreement will be transferred or paid into the Bioprospecting Trust Fund;

(b) notify stakeholders entitled to a monetary benefit in terms of a benefit-sharing agreement that money was transferred or paid into the Bioprospecting Trust Fund.

Part 2: Administration of the Bioprospecting Trust Fund

19. The administration of the Bioprospecting Trust Fund

(1) In terms of section 85(1) of the Act, all money arising from benefit-sharing agreements and due to stakeholders must be paid into the Bioprospecting Trust Fund.

(2) The Bioprospecting Trust Fund will be managed in accordance with Treasury Regulations issued in terms of the Public Finance Management Act, 1999 (Act No.1 of 1999).

(3) For the purposes of adhering to Treasury Regulations –
(a) each benefit-sharing agreement must be regarded as the trust instrument that details the specific purpose for which money received by the Bioprospecting Trust Fund may be used;

(b) the Director-General is responsible for the safekeeping and proper use of all money received by the Bioprospecting Trust Fund, in accordance with the relevant benefit-sharing agreement;

(c) the Director-General may charge a reasonable fee for the administration of money received in terms of a benefit-sharing agreement;

(4) The Director-General must-

(a) notify all issuing authorities of the banking details of the Bioprospecting Trust Fund, which details must be handed to permit-holders on issuance of every permit;

(b) advise parties to a benefit-sharing agreement of -

(i) any money received in respect of that agreement;

(ii) the amount due to each stakeholder in terms of the agreement; and

(c) distribute all monies received in accordance with the relevant benefit-sharing agreement.

(5) The Director-General’s obligations in terms of sub-regulation (4) may be discharged annually unless a different time period is-

(a) stipulated in the relevant benefit-sharing agreement; or

(b) agreed between the Director-General and the parties to a benefit-sharing agreement.

(6) If for whatever reason, there is surplus money in the Bioprospecting Trust Fund that is not due to any party in terms of a benefit-sharing agreement, the Director-General must use the money for one or more of the following purposes-

(a) to conserve the indigenous biological resources;

(b) to support further research on indigenous biological resources and indigenous knowledge;

(c) to build capacity amongst indigenous communities-
(i) as to their rights in terms of the Act; and

(ii) to enable them to negotiate benefit-sharing agreements that are fair and equitable;

(d) to enhance scientific knowledge and technical capacity to conserve, use and develop indigenous biological resources; or

(e) any other activity that promotes the conservation, sustainable use and development of indigenous biological resources for the benefit of South Africa.

(7) If it is not possible, for whatever reason, to pay any party money due to them in terms of a benefit-sharing agreement, the Director-General must-

(a) ascertain if there is another person or body to whom the money should legally be paid;

(b) if there is no identifiable person or body to whom the money must be paid, consult any other parties to the relevant agreement as to the distribution of that money and thereafter distribute the money fairly and equitably between remaining stakeholders, if any;

(c) if there are no other stakeholders, distribute the money in accordance with sub-regulation (6).

CHAPTER 4: GENERAL

20. Offences

A person is guilty of an offence if that person-

(a) without a permit-

(i) undertakes bioprospecting involving indigenous biological resources;

(ii) exports from the Republic any indigenous biological resources for the purpose of bioprospecting or any other research;

(b) performs the activity for which the permit was issued otherwise than in accordance with any conditions subject to which a permit was issued;

(c) permits or allow any other person to do, or to omit to do anything which is an offence in terms of these regulations;
21. **Penalties**

(1) A person convicted of an offence in terms of regulation 20 is liable to-

(a) imprisonment for a period not exceeding five years;
(b) an appropriate fine; or
(c) to both a fine and such imprisonment.

(2) A fine in terms of sub-regulation (1) may not exceed an amount prescribed in terms of the Adjustment of Fines Act, 1991 (Act No. 101 of 1991).

22. **Transitional provisions**

(1) Subject to sub-regulations (2) and (3), any person involved at the commencement of these Regulations in a bioprospecting project, may continue with that project pending the issuing of a bioprospecting permit.

(2) A person involved in a bioprospecting project that has already commenced must, within six months of these Regulations coming into effect, submit an application for a bioprospecting permit to the Minister in accordance with Chapter 2 of these Regulations.

(3) If a bioprospecting project that has already commenced involves stakeholder interests that are required to be protected by section 82 of the Act, the applicant for a bioprospecting permit must -

(a) negotiate and enter into appropriate benefit-sharing agreements with identified stakeholders;

(b) attach to the application for a bioprospecting permit submitted to the Minister in terms of sub-regulation (2)-

(i) signed benefit-sharing agreements entered into with stakeholders; or

(ii) a written request for the intervention of the Minister for the purposes of negotiating such agreements, in accordance with section 82(4)(b) of the Act, if it has not been possible to conclude benefit-sharing agreements within the six months referred to in sub-regulation (2).

(4) A bioprospecting project that has already commenced -

(a) must be terminated if-
(i) an application for a bioprospecting permit is refused; or

(ii) a benefit-sharing agreement is not concluded notwithstanding the intervention of the Minister;

(b) may continue if a bioprospecting permit is issued, subject to any conditions contained in that permit.

23. Short Title and commencement

These Regulations are called Bioprospecting, Access and Benefit-Sharing Regulations, 2008 and will come into operation on a date fixed by the Minister by notice in the Gazette.

ANNEXURE 1:
PRESCRIBED NON-REFUNDABLE FEES

1. Permit fees

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2. Appeal in terms of Regulation 15

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ANNEXURE 2:
PART 1: APPLICATION FOR A BIOPROSPECTING PERMIT
PART 2: APPLICATION FOR AN EXPORT PERMIT FOR THE PURPOSES OF BIOPROSPECTING

ANNEXURE 3:
APPLICATION FOR AN EXPORT PERMIT FOR THE PURPOSES OF CONDUCTING RESEARCH OTHER THAN BIOPROSPECTING

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