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# NATIONAL ENVIRONMENTAL MANAGEMENT: BIODIVERSITY ACT 10 OF 2004

## BIOPROSPECTING, ACCESS AND BENEFIT-SHARING AMENDMENTS REGULATIONS, 2015

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I, Bomo Edith Edna Molewa, Minister of Environmental Affairs, hereby make regulations in terms of section 97(1), (e), (f), (g), and (h) of the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004), set out in the Schedule hereto.

**(Signed)**
**BOMO EDITH EDNA MOLEWA**
**MINISTER OF ENVIRONMENTAL AFFAIRS**

### SCHEDULE

### CHAPTER 1
### INTERPRETATION, PURPOSE, AND APPLICATION OF REGULATIONS

1. Definitions
2. Purpose of Regulations
3. Application of these Regulations

### CHAPTER 2
### ISSUING AUTHORITY

4. Identification of issuing authority
5. Where to submit notifications or permit applications
6. Assistance by issuing authority to applicant or stakeholder
7. Consultation between issuing authority and relevant stakeholders
8. Issuing authority's right of access to information
9. Criteria to be taken into account by issuing authority when considering notifications or permit applications
10. Communication of decision on notifications or permit applications by the issuing authority
11. Registry of notifications, permit applications, and record of decisions

### CHAPTER 3
### PERMIT SYSTEM FOR BIOPROSPECTING AND FOR RESEARCH OTHER THAN BIOPROSPECTING

Part 1: Specification of applicants for permit or to notify

12. Applicant

Part 2: Discovery Phase of Bioprospecting

13. Notification
14. Discovery phase export permit

Part 3: Commercialisation Phase of Bioprospecting

15. Permit
16. Biotrade permit
17. Bioprospecting permit
18. Integrated biotrade and bioprospecting permit

Part 4: Research other than Bioprospecting

19. Export permit for research other than bioprospecting

Part 5: Procedures for submission of notifications or permit applications

20. Submission of notifications or permit applications

Part 6: Consideration of notifications or permit applications

21. Timeframes for issuing authority
22. Factors to be taken into account by issuing authority when considering notifications
23. Factors to be taken into account by issuing authority when considering discovery phase export permit applications
24. Factors to be taken into account by issuing authority when considering biotrade permit applications
25. Factors to be taken into account by issuing authority when considering bioprospecting permit applications
26. Factors to be taken into account by issuing authority when considering integrated biotrade and bioprospecting permit applications
27. Factors to be taken into account by issuing authority when considering export permit applications for research other than bioprospecting

Part 7: Refusal of notification or permit

28. Circumstances in which notifications or permits must be refused

Part 8: Registration of Notifications

29. Decision of issuing authority on notification
30. Compulsory conditions applicable to notifications

Part 9: Issuing of permits

31. Decision of issuing authority on permit applications
32. Content of permits
33. Compulsory conditions applicable to permit holders
34. Period of validity of permits

Part 10: Renewal or Amendment of permit

35. Applications for renewal or amendment of permits by Permit Holders
36. Consideration of and decision on permit renewal applications
37. Consideration of and decision on permit amendment applications

**CHAPTER 4**
**MATERIAL TRANSFER AGREEMENTS, BENEFIT-SHARING AGREEMENTS AND THE ADMINISTRATION OF THE BIOPROSPECTING TRUST FUND**

Part 1: Agreements

38. Material transfer agreement
39. Benefit-sharing agreement

Part 2: Administration of the Bioprospecting Trust Fund

40. The administration of the Bioprospecting Trust Fund

**CHAPTER 5**
**GENERAL MATTERS**

41. Offences
42. Penalties
43. Repeal of the Bioprospecting, Access and Benefit-Sharing Regulations, 2008

**CHAPTER 6**

**TRANSITIONAL PROVISIONS**

44. Continuation of regulated activities and permit issued in terms of the Bioprospecting, Access, and Benefit-Sharing Regulations, 2008
45. Pending applications for permits and appeals lodged in terms of the Bioprospecting, Access and Benefit-Sharing Regulations, 2008
46. Short title and commencement

ANNEXURE 1: DISCOVERY PHASE NOTIFICATION FORM

ANNEXURE 2: APPLICATION FORM FOR A DISCOVERY PHASE EXPORT PERMIT

ANNEXURE 3: APPLICATION FOR AN EXPORT PERMIT FOR RESEARCH OTHER THAN BIOPROSPECTING

ANNEXURE 4: NON-REFUNDABLE FEES FOR PERMITS APPLICATION

ANNEXURE 5: APPLICATION FORM FOR A BIOPROSPECTING PERMIT OR BIOTRADE PERMIT OR INTEGRATED BIOTRADE AND BIOPROSPECTING PERMIT

ANNEXURE 6: DISCOVERY PHASE EXPORT PERMIT

ANNEXURE 7: EXPORT PERMIT FOR RESEARCH OTHER THAN BIOPROSPECTING

ANNEXURE 8: BIOTRADE PERMIT

ANNEXURE 9: BIOPROSPECTING PERMIT

ANNEXURE 10: INTEGRATED BIOTRADE AND BIOPROSPECTING PERMIT

ANNEXURE 11: MATERIAL TRANSFER AGREEMENT

ANNEXURE 12: BENEFIT-SHARING AGREEMENT

ANNEXURE 13: COMMUNITY RESOLUTION

## CHAPTER 1
## INTERPRETATION, PURPOSE AND APPLICATION OF REGULATIONS

### 1. Definitions

In these Regulations any word or expression to which a meaning has been assigned in the Act has that meaning, and unless the context requires otherwise-

**"applicant"** means a person who has submitted a permit application or notification in terms of these Regulations;

**"benefit-sharing agreement"** means an agreement in the form of Annexure 12 to these Regulations, concluded between an applicant for a permit and a stakeholder or stakeholders identified in terms of section 82(1)(a) and (b) of the Act, which provides for sharing by the stakeholder or stakeholders in any future benefits that may be derived from bioprospecting to which the application relates;

**"permit"** means a permit issued in terms of these Regulations read with Chapter 7 of the Act;

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

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

**"confidential information"** means information which, if disclosed, may be detrimental to the commercial, associated traditional knowledge 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) traditional knowledge if the disclosure of that knowledge may be detrimental to the relevant indigenous community or specific individual; but

(b) excludes information-

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

(ii) if the parties consent to its disclosure;

**"Department"** means the Department responsible for environmental affairs;

**"material transfer agreement"** means an agreement in the form of Annexure 11 to these Regulations, concluded between an applicant for a permit and a stakeholder or stakeholders identified in terms of section 82(1)(a) of the Act, which provides for or giving access to the indigenous genetic and biological resources to which the application relates;

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

**"the Act"** means the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004);

**"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.

**2. Purpose of Regulations**

(1) The purpose of the Regulations is to-

(a) prescribe the notification process for the discovery phase of bioprospecting involving any indigenous genetic and biological resources contemplated in section 81A(2) of the Act;

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

(c) set out the form and content of, and requirements and criteria for benefit-sharing and material transfer agreements; and

(d) set out the administration process of the Bioprospecting Trust Fund.

**3. Application of these Regulations**

(1) These Regulations apply to-

(a) commercial or industrial sectors that utilize any indigenous genetic and biological resources for biotrade or for research, application or development of drugs, complementary medicines, neutraceuticals, industry enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts, and essential oils.

(b) commercial or industrial sectors that utilize traditional knowledge associated with any indigenous genetic and biological resources for biotrade or for research, application or development of drugs, complementary medicines, neutraceuticals, industry enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts, and essential oils.

(c) non-commercial sectors that export from the Republic any indigenous genetic and biological resources for a research to generate scientific data.

## CHAPTER 2
## ISSUING AUTHORITY

**4. Identification of issuing authority**

(1) The Minister is the issuing authority in terms of section 1 of the Act for-

(a) discovery phase export permits;

(b) biotrade permits;

(c) bioprospecting permits; or

(d) integrated biotrade and bioprospecting permits.

(2) The MEC is the issuing authority in terms of section 1 of the Act for-

(a) export permit for research other than bioprospecting.

**5. Where to submit notifications and applications**

(1) The notification to the Minister contemplated in section 81A of the Act must be submitted to the Department.

(2) If the Minister is the issuing authority in respect of an application for any of the permits contemplated in regulations 14 and 15 of these Regulations, such application must be submitted to the Department.

(3) If the Minister has assigned or delegated powers and duties contemplated in regulation 3(1) and (2) of these Regulations to the MEC, the application must be submitted to the relevant provincial department responsible for environmental affairs.

(4) The export permit for research other than bioprospecting contemplated in regulation 19 of these Regulations, must be submitted to the relevant provincial department responsible for environmental affairs, if the indigenous genetic and biological resources to be exported are collected or gathered in that province.

**6. Assistance by issuing authority to applicant or stakeholder**

(1) The issuing authority may upon request by an applicant or stakeholder-

(a) give the applicant or stakeholder access to any guidelines, information on practices that have been developed or any other information in the possession of the issuing authority that is relevant to the permit application; or

(b) advise the applicant or stakeholder, either in writing or by way of discussions, of the nature and extent of any of the processes that must be followed in order to comply with the Act and these Regulations, provided that such advice, discussion or the lack thereof, shall in no way impact on the applicant's duty to comply with the provisions of the Act or these Regulations.

(2) The issuing authority may, on written request, furnish the applicant or stakeholder with officially adopted minutes of any meeting held or discussion that took place, contemplated in subregulation (1) (b), between the issuing authority and the applicant or stakeholder.

**7. Consultation between the issuing authority and relevant stakeholders**

(1) The issuing authority may consult with the relevant stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act, after the submission of an application by the applicant for any of the permits contemplated in regulations 14 and 15 of these Regulations.

(2) When consulting with the relevant stakeholder or stakeholders the issuing authority must have regard to section 82(4) of the Act as well as protecting any interests that the stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act may have in the proposed bioprospecting project.

**8. Issuing authority's right of access to information**

(1) The issuing authority is entitled to all information that reasonably has or may have the potential to influence any decision with regard to an application for any of the permits contemplated in regulations 14, 15, and 19 of these Regulations unless access to that information is protected by law.

(2) Unless access to the information contemplated in subregulation (1) is protected by law, an applicant or relevant stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act in possession of that information must, on request by the issuing authority, disclose that information to the issuing authority, whether or not such information is favourable to the applicant.

**9. Criteria to be taken into account by issuing authority when considering notifications or permit applications**

(1) When considering a notification contemplated in regulation 13 of these Regulations or an application for any of the permits contemplated in regulations 14, 15, and 19 of these Regulations, the issuing authority must-

(a) comply with the Act;

(b) take into account all relevant factors, which may include-

(i) documentary proof that the relevant stakeholders have been identified by the applicant in accordance with section 82(1) of the Act;

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

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

(iv) documentary proof that the applicant has obtained the prior consent of affected indigenous communities or individuals, and benefit-sharing agreements have been entered into with such communities or individuals;

(v) any comments received from the relevant stakeholders or affected indigenous communities or individuals during the consultation meetings between the issuing authority and relevant stakeholders;

(vi) the conservation of biodiversity in South Africa;

(vii) the economic development of South Africa;

(viii) enhancement of the scientific knowledge and technical capacity of South African citizen and institutions;

(ix) any guidelines and departmental policies that have been adopted or any other information in the possession of the issuing authority that is relevant to the application;

(x) any alleged non-compliance by the applicant with any of the provisions of the Act;

(xi) all the information and documentation contained in the application form and submitted by the applicant, including any additional information requested by the issuing authority in terms of the Act or these Regulations; and

(xii) documentary proof that the affected indigenous community has adopted a community resolution authorizing a representative to give prior consent to the applicant, giving access to indigenous genetic and biological resources and traditional knowledge associated with the use of indigenous genetic and biological resource and to further enter into benefit sharing and material transfer agreements on behalf of the indigenous community.

**10. Communication of decision on notifications or permit applications by the Issuing authority**

After an issuing authority has reached a decision on any of the applications for a permit contemplated in regulations 14, 15, and 19 of these Regulations, the issuing authority must, in writing and within 15 (fifteen) working days-

(a) inform the applicant of the decision;

(b) inform the stakeholders contemplated in section 82(1) (a) and (b) of the Act, of the decision; and

(c) on written request give reasons for the decision to the applicant or stakeholders.

**11. Registry of notifications, permit applications, and record of decisions**

The issuing authority must keep-

(a) a register of all permit applications received in terms of these Regulations;

(b) a register of all notifications received in terms of these Regulations

(c) records of all decisions in respect of the permit applications; and

(d) records of all decisions in respect of the Material Transfer Agreements and the Benefit Sharing Agreements by the Minister.

## CHAPTER 3
## PERMIT SYSTEM FOR BIOPROSPECTING AND FOR RESEARCH OTHER THAN BIOPROSPECTING

### Part 1: Specification of applicants for Permits or to Notification

**12. Applicant**

A permit or notification in terms of the Act may only be issued to or submitted by-

(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; or

(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.

### Part 2: Discovery phase of bioprospecting

**13. Notification**

(1) The notification to the Minister contemplated in section 81A of the Act by any person who engages in the discovery phase of bioprospecting involving any indigenous genetic and biological resources or associated traditional knowledge must be submitted in the form of Annexure 1 to these Regulations.

(2) A notification must be accompanied by proof that prior consent of the stakeholder or stakeholders contemplated in section 82(1) (a) and (b) of the Act for the provision of or access to the indigenous genetic and biological resources or associated traditional knowledge, has been obtained.

**14. Discovery phase export permit**

(1) A person who wishes to export from the Republic any indigenous genetic and biological resources for the purpose of bioprospecting for commercial research must obtain a discovery phase export permit from the issuing authority.

(2) An application for a discovery phase export permit must be submitted in the form of Annexure 2 to these Regulations.

(3) An application for a discovery phase export permit must be accompanied by the following:

(a) notification to the Minister in the form of Annexure 1 of these Regulations

(b) proof of prior consent from the stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act for the provision of or access to the indigenous genetic and biological resources and/or associated traditional knowledge;

(c) signed material transfer agreement between the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) of the Act for the provision of or access to the indigenous genetic and

biological resources;

(d) signed benefit-sharing agreement between the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act for the provision of access to the indigenous genetic and biological resources or traditional knowledge associated with indigenous genetic and biological resources; and

(e) non-refundable fee specified in Annexure 4 to these Regulations.

**Part 3: Commercialisation phase of bioprospecting permits**

**15. Permit**

Commercialisation phase of bioprospecting may be authorised in terms of any of the following permits:

(a) biotrade permit;

(b) bioprospecting permit; or

(c) integrated biotrade and bioprospecting permit.

**16. Biotrade permit**

(1) A person who wishes to engage in biotrade within the Republic, must obtain a biotrade permit from the issuing authority.

(2) A biotrade permit referred to in paragraph (1) above, may also be used for export from the Republic of any indigenous genetic and biological resources covered in the permit application.

(3) An application for a biotrade permit must be submitted in the form of Annexure 5 to these Regulations.

(4) An application for a biotrade permit must be accompanied by the following:

(a) proof of prior consent from the stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act for the provision of access to the indigenous genetic and biological resources or traditional knowledge associated with indigenous genetic and biological resources;

(b) signed material transfer agreement between the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) of the Act for the provision of access to the indigenous genetic and biological resources;

(c) signed benefit-sharing agreement between the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act; or

(d) if it has not been possible to conclude agreements referred to in paragraphs (b) or (c) above, a request for the intervention of the issuing authority for the purposes of facilitating the negotiations for such agreement in accordance with section 82(4) (b) of the Act; and

(e) non-refundable fee specified in Annexure 4 to these Regulations.

(5) An application for a biotrade permit by a subsequent trader of indigenous genetic and biological resources purchased from a holder or holders of the biotrade permit issued in terms of these Regulations, must be submitted in the form of Annexure 5 to these Regulations and must be accompanied by-

(a) a letter of consent from the permit holder or holders, including how the legal obligation of the subsequent trader in terms of section 82 of the Act will be covered by the existing biotrade permit; and

(b) a non-refundable fee specified in Annexure 4 of these Regulations.

**17. Bioprospecting permit**

(1) A person who engages in bioprospecting involving any indigenous genetic and biological resources within the Republic, must obtain a bioprospecting permit from the issuing authority.

(2) A bioprospecting permit referred to in paragraph (1) above, may also be used for export from the Republic of any indigenous genetic and biological resources covered in the permit application.

(3) An application for a bioprospecting permit must be submitted in the form of Annexure 5 to these Regulations.

(4) An application for a bioprospecting permit must be accompanied by the following:

(a) proof of prior consent from the stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act for the provision of access to the indigenous genetic and biological resources or traditional knowledge associated with indigenous genetic and biological resources;

(b) signed material transfer agreement between the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) of the Act for the provision of access to the indigenous genetic and biological resources;

(c) signed benefit-sharing agreement, between the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act, or

(d) if it has not been possible to conclude agreements referred to in paragraphs (b) or (c) above, a request for the intervention of the issuing authority for the purposes of facilitating the negotiations for such agreement in accordance with section 82(4) (b) of the Act; and

(e) non-refundable fee specified in Annexure 4 to these Regulations.

**18. Integrated biotrade and bioprospecting permit**

(1) A person who wishes to engage in both biotrade and bioprospecting involving indigenous genetic and biological resources within the Republic, must obtain an integrated biotrade and bioprospecting permit from the issuing authority.

(2) An integrated biotrade and bioprospecting permit referred to in paragraph (1) above, may also be used for export from the Republic of any indigenous genetic and biological resources covered in the permit application.

(3) An application for an integrated biotrade and bioprospecting permit must be submitted in the form of Annexure 5 to these Regulations.

(4) An application for an integrated biotrade and bioprospecting permit must be accompanied by the following:

(a) proof of prior consent from the stakeholder or stakeholders contemplated in section 82(1) (a) and (b) of the Act for the provision of or access to the indigenous genetic and biological resources or traditional knowledge associated with indigenous genetic and biological resources;

(b) signed material transfer agreement between the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) of the Act for the provision of access to the indigenous genetic and biological resources;

(c) signed benefit-sharing agreement, if such an agreement has been signed between the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act, or

(d) if it has not been possible to conclude such agreements referred to in paragraphs (b) or (c) above,, a request for the intervention of the issuing authority for the purposes of facilitating the negotiations for such agreement in accordance with section 82(4)(b) of the Act; and

(e) non-refundable fee specified in Annexure 4 to these Regulations.

## Part 4: Research other than Bioprospecting

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

(1) A person who wishes to export from the Republic any indigenous genetic and biological resources for research other than bioprospecting must obtain an export permit for research other than bioprospecting from the issuing authority.

(2) An application for an export permit for research other than bioprospecting must be submitted in the form of Annexure 3 to these Regulations.

(3) An application for an export permit for research other than bioprospecting must be accompanied by the following:

(a) the specification of the indigenous genetic and biological resources involved;

(b) the specification of the quantity of the indigenous genetic and biological resources involved;

(c) the specification of the source of the indigenous genetic and biological resources;

(d) the purpose for which such indigenous genetic and biological resources are to be exported; and

(e) non-refundable fee specified in Annexure 4 to these Regulations.

**Part 5: Procedures for submission of Notifications and Permit Applications**

**20. Submission of notifications and permit applications**

(1) A notification contemplated in regulation 13 of the Regulations and a permit application contemplated in regulations 14, 15, and 19 of these Regulations must be submitted to the issuing authority in the following manner:

(a) by e-mail;

(b) by registered mail;

(c) by ordinary mail;

(d) by hand delivery;

(e) by fax; or

(f) electronically on-line.

(2) A notification contemplated in regulation 13 of these Regulations must contain all information that is required in the notification form set out in Annexure 1 to these Regulations.

(3) An application for any of the permits contemplated in regulations 14, 15, and 19 of these Regulations must contain all information that is required in the prescribed application forms.

**Part 6: Consideration of permit applications**

**21. Timeframes for issuing authority**

(1) On receipt of a notification contemplated in regulation 13 of these Regulations or an application for a permit contemplated in regulations 14, 15, and 19 of these Regulations, the issuing authority must, if satisfied that all the prescribed and requested information has been submitted, consider and decide such an application within 120 (hundred and twenty) working days after date of receipt of such an application.

(2) Where the issuing authority requires additional information to be submitted by the applicant, the issuing authority must within 10 (ten) working days after the date of receipt of such an application and in writing, request the applicant to submit such information within 20 (twenty) working days after date of receipt of such a request.

(3) If the additional information requested is not submitted to the issuing authority within 30 (thirty) working days after such a request, such an application must be deemed withdrawn.

(4) If the information submitted by the applicant to the issuing authority is sufficient, but the issuing authority is unable to comply with the timeframe contemplated in subregulation (1), the issuing authority must-

(a) indicate in writing to the applicant, prior to the lapsing of the timeframe contemplated in subregulation (1), that such an application will be decided within 30 (thirty) working days after the lapsing of the timeframe contemplated in subregulation (1); and

(b) provide written reasons to the applicant, prior to the lapsing of the timeframe contemplated in subregulation (1), why the issuing authority will not be able to comply with the timeframe contemplated in subregulation (1).

(5) Upon the lapsing of the extension contemplated in subregulation (4), the provisions of section 6(2)(g) and (3) of the Promotion of Administrative Justice Act, 2000 will apply.

**22. Factors to be taken into account by issuing authority when considering notifications**

When considering a notification for a discovery phase of bioprospecting, the issuing authority must take into consideration the following factors, in addition to the factors set out in regulation 9 of these Regulations and the procedures outlined in regulation 13 of these Regulations:

(a) assess the manner in which the potential impact of the discovery phase of bioprospecting on the indigenous genetic and biological resources will be minimized and remedied;

(b) assess that the impact of the discovery phase of bioprospecting on the indigenous genetic and biological resources will be negligible or will not deplete an indigenous genetic and biological resource beyond a level where its integrity is jeopardized.

**23. Factors to be taken into account by issuing authority when considering discovery phase export permits**

When considering an application for a discovery phase export permit, the issuing authority must also take into consideration the following factors, in addition to the factors set out in regulation 9 of these Regulations and the procedures outlined in regulation 14 of these Regulations:

(a) assess the manner in which the potential impact of the discovery phase of bioprospecting on the indigenous genetic and biological resources will be minimized and remedied;

(b) assess that the impact of the discovery phase of bioprospecting on the indigenous genetic and biological resources will be negligible or will not deplete an indigenous genetic and biological resource beyond a level where its integrity is jeopardized.

**24. Factors to be taken into account by issuing authority when considering biotrade permits**

When considering an application for a biotrade permit, the issuing authority must also take into consideration the following factors, in addition to the factors set out in regulation 9 of these Regulations and the procedures outlined in regulation 16 of these Regulations:

(a) assess the manner in which the potential impact of the biotrade on the indigenous genetic and biological resources will be minimized and remedied;

(b) assess that the impact of the biotrade on the indigenous genetic and biological resources will be negligible or will not deplete an indigenous genetic and biological resource beyond a level where its integrity is jeopardized.

**25. Factors to be taken into account by issuing authority when considering bioprospecting permits**

When considering an application for a bioprospecting permit, the issuing authority must also take into consideration the following factors, in addition to the factors set out in regulation 9 of these Regulations and the procedures outlined in regulation 17 of these Regulations:

(a) assess the manner in which the potential impact of the bioprospecting on the indigenous genetic and biological resources will be minimized and remedied;

(b) assess that the impact of the bioprospecting on the indigenous genetic and biological resources will be negligible or will not deplete an indigenous genetic and biological resource beyond a level where its integrity is jeopardized.

**26. Factors to be taken into account by issuing authority when considering integrated biotrade and bioprospecting permits**

When considering an application for integrated biotrade and bioprospecting permit, the issuing authority must also take into consideration the following factors, in addition to the factors set out in regulation 9 of these Regulations and the

procedures outlined in regulation 18 of these Regulations:

(a) assess the manner in which the potential impact of the integrated biotrade and bioprospecting on the indigenous genetic and biological resources will be minimized and remedied;

(b) assess that the impact of the integrated biotrade and bioprospecting on the indigenous genetic and biological resources will be negligible or will not deplete an indigenous genetic and biological resource beyond a level where its integrity is jeopardized.

**27. Factors to be taken into account by issuing authority when considering export permits for research other than bioprospecting**

When considering an application for an export permit for research other than bioprospecting, the issuing authority must also take into consideration the following factors, in addition to the factors set out in regulation 9 of these Regulations and the procedures outlined in regulation 19 of these Regulations:

(a) assess the manner in which the potential impact of the research other than bioprospecting on the indigenous genetic and biological resources will be minimized and remedied;

(b) assess that the impact of the research other than bioprospecting on the indigenous genetic and biological resources will be negligible or will not deplete an indigenous genetic and biological resource beyond a level where its integrity is jeopardized.

## Part 7: Refusal of notification or permit

**28. Circumstances in which notifications and permits must be refused**

(1) The issuing authority must refuse to register a notification set out in regulation 13 of these Regulations if the applicant fails to comply with any of the legal requirements set out in regulations 9, and 22 of these Regulations.

(2) The issuing authority must refuse to issue any of the permits set out in regulations 14, 15, and 19 of these Regulations if the applicant fails to comply with any of the legal requirements set out in regulations 9, 23, 24, 25, 26, and 27 of these Regulations.

(3) Notifications that do not comply with the requirements set out in regulation 13 are deemed to be incomplete and will not be considered by the issuing authority.

(4) Applications that do not comply with the requirements set out in regulations 14, 16, 17, 18, and 19 are deemed to be incomplete and will not be considered by the issuing authority.

## Part 8: Registration of Notification

**29. Decision of issuing authority on notifications**

(1) The issuing authority may only register the notification contemplated in regulation 13 of these Regulations if the applicant complies with the legal requirements set out in regulations 9, and 22 of these Regulations.

(2) The issuing authority may consult, before making a decision on any of the notifications contemplated in regulation 13 of these Regulations, any person or persons competent to provide technical advice.

(3) If the decision of the issuing authority is to register the notification contemplated in regulation 13 of these Regulations subject to certain conditions, the issuing authority must-

(a) give written reasons for the decision to the applicant, if required by the applicant; and

(b) inform the applicant of his or her right to appeal against the decision of the issuing authority to the relevant appeal authority.

(4) If the decision of the issuing authority is to refuse to register the notification contemplated in regulation 13 of these Regulations, the issuing authority must, in addition to the legal requirement set out in section 88(5) of the Act, inform the applicant of his or her right to appeal against the decision of the issuing authority to the relevant appeal authority.

(5) The issuing authority must not register a notification contemplated in regulation 13 of these Regulations with retrospective effect.

**30. Compulsory conditions applicable to notifications**

(1) The notification to the Minister contemplated in section 81A(1) of the Act must be subject to the conditions that the-

(a) applicant must, on an annual basis or such alternative timeframe as determined by the issuing authority, submit a status report on the discovery phase of the bioprospecting to the issuing authority in a format determined by the issuing authority.

(b) permit holder is liable for the costs of mitigating or remedying the impact of discovery phase of bioprospecting on the environment, in accordance with section 28 of the NEMA.

**Part 9: Issuing of permits**

**31. Decision of issuing authority on permit applications**

(1) The issuing authority may only issue any of the permit contemplated in regulations 14, 15, and 19 of these Regulations if the applicant complies with the legal requirements set out in regulations 9, 23, 24, 25, 26, and 27 of these Regulations.

(2) The issuing authority may consult, before making a decision on any of the permits contemplated in regulations 14, 15, and 19 of these Regulations, any person or persons competent to provide technical advice.

(3) If the decision of the issuing authority is to grant any of the permits contemplated in regulations 14, 15, and 19 of these Regulations subject to certain conditions, the issuing authority must-

(a) give reasons for the decision to the applicant if required by the applicant; and

(b) inform the applicant of his or her right to appeal against the decision of the issuing authority to the relevant appeal authority.

(4) If the decision of the issuing authority is to refuse the application for any of the permits contemplated in regulations 14, 15, and 19 of these Regulations, the issuing authority must, in addition to the legal requirement set out in section 88(5) of the Act, inform the applicant of his or her right to appeal against the decision of the issuing authority to the relevant appeal authority.

(5) The issuing authority must not issue any of the permits contemplated in regulations 14, 15, and 19 of these Regulations with retrospective effect.

**32. Content of permits**

(1) A discovery phase export permit must be issued in the prescribed form set out in Annexure 6 to these Regulations.

(2) A biotrade permit must be issued in the prescribed form set out in Annexure 8 to these Regulations.

(3) A bioprospecting permit must be issued in the prescribed form set out in Annexure 9 to these Regulations.

(4) An integrated biotrade and bioprospecting permit must be issued in the prescribed form set out in Annexure 10 to these Regulations.

(5) An export permit for research other than bioprospecting must be issued in the prescribed form set out in Annexure 7 to these Regulations.

**33. Compulsory conditions applicable to permit holders**

(1) A discovery phase export permit must be issued subject to the conditions that the-

(a) permit holder must, on an annual basis or such alternative timeframe as determined by the issuing authority, submit a status report on the discovery phase of the bioprospecting to the issuing authority in a

format determined by the issuing authority;

(b) permit holder is liable for the costs of mitigating or remedying the impact of discovery phase of bioprospecting on the environment, in accordance with section 28 of the NEMA; and

(c) indigenous genetic and 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.

(2) A biotrade permit must be issued subject to the conditions that-

(a) 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;

(b) the permit holder must notify the Department when money due to stakeholders as specified in the benefit-sharing agreement will be transferred or paid into the Bioprospecting Trust Fund;

(c) the permit holder must notify the stakeholder or stakeholders entitled to a monetary benefit in terms of the benefit-sharing agreement that money was transferred or paid into the Bioprospecting Trust Fund;

(d) the permit holder must, on an annual and biannual basis or such alternative timeframe as determined by the issuing authority, submit a status report to the issuing authority in a format determined by the issuing authority; and

(e) the permit holder is liable for the costs of mitigating or remedying the impact of biotrade on the environment, in accordance with section 28 of the NEMA.

(3) A bioprospecting permit must be issued subject to the conditions that-

(a) 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;

(b) the permit holder must notify the Department when money due to stakeholders as specified in the benefit-sharing agreement will be transferred or paid into the Bioprospecting Trust Fund;

(c) the permit holder must notify stakeholder or stakeholders entitled to a monetary benefit in terms of the benefit-sharing agreement that money was transferred or paid into the Bioprospecting Trust Fund;

(d) the permit holder must, on an annual basis or such alternative timeframe as determined by the issuing authority, submit a status report to the issuing authority in a format determined by the issuing authority;

(e) the indigenous genetic and biological resources to which a permit relates may not be sold, donated or transferred to a third party without the written consent of the issuing authority; and

(f) the permit holder is liable for the costs of mitigating or remedying the impact of bioprospecting on the environment, in accordance with section 28 of the NEMA.

(4) An integrated biotrade and bioprospecting permit must be issued subject to the conditions that-

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

(b) the permit holder must notify the Department when money due to stakeholders as specified in the benefit-sharing agreement will be transferred or paid into the Bioprospecting Trust Fund;

(c) the permit holder must notify stakeholder or stakeholders entitled to a monetary benefit in terms of the benefit-sharing agreement that money was transferred or paid into the Bioprospecting Trust Fund;

(d) the permit holder must, on an annual basis or such alternative timeframe as determined by the issuing authority, submit a status report to the issuing authority in a format determined by the issuing authority;

(e) the indigenous genetic and biological resources to which a bioprospecting component of a permit relates may not be sold, donated or transferred to a third party without the written consent of the issuing authority; and

(f) the permit holder is liable for the costs of mitigating or remedying the impact of integrated biotrade and bioprospecting on the environment, in accordance with section 28 of the NEMA.

(5) An export permit for research other than bioprospecting must be issued subject to the conditions that-

(a) the indigenous genetic and biological resources to which the permit relates may only be used for non-commercial research purposes as specified in the permit;

(b) the indigenous genetic and biological resources to which the permit relates may not be used for bioprospecting;

(c) 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;

(d) the indigenous genetic and 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 indigenous genetic and biological resources for bioprospecting purposes; and

(e) the permit holder must, on an annual basis or such alternative timeframe as determined by the issuing authority, submit a status report to the issuing authority in a format determined by the issuing authority.

**34. Period of validity of permits**

(1) Any of the permits contemplated in regulations 14, 15, and 19 of these Regulations is only valid for specific period, and involves only the indigenous genetic and biological resources relating to such permit.

(2)

(a) A discovery phase export permit may be issued for a permitted use.

(b) A biotrade permit may be issued with a period of validity not exceeding 5 (five) years.

(c) A bioprospecting permit may be issued with a period of validity not exceeding 5 (five) years.

(d) An integrated biotrade and bioprospecting permit may be issued with a period of validity not exceeding 5 (five) years.

(e) An export permit for research other than bioprospecting may be issued for permitted use.

**Part 10: Renewal or Amendment of permit**

**35. Applications for renewal or amendment of permits by Permit Holders**

(1) A permit holder may, before the expiry date of a permit, apply to an issuing authority for the renewal of such permit.

(2) A permit holder may, after the first annual project status reporting, apply at any time to an issuing authority for the amendment of such permit.

(3) An application for the renewal or amendment of a permit must be submitted in the form of Annexure 2, 3, or 5 to these Regulations.

(4) An application for the renewal or amendment of a permit must be accompanied by a non-refundable fee specified in Annexure 4 of these Regulations.

**36. Consideration of and decision on permit renewal applications**

(1) On receipt of an application in terms of regulation 36 of these Regulations, an issuing authority -

(a) must have regard to the same matters which it was required to consider when deciding on the initial application for that permit;

(b) must have regard to the permit conditions subject to which the permit was issued were complied with by the permit holder;

(c) must consider how the conservation status of the indigenous genetic and biological resources has been maintained or sustainably utilised;

(d) If the conservation status of the species has deteriorated, the issuing authority may request a risk assessment to be submitted prior to considering renewal of the permit;

(e) may for good reason amend or substitute any condition attached to a permit and any new information at the time of the renewal application; and

(f) may require the applicant to furnish additional information.

(2) After having reached a decision on an application for renewal, the issuing authority must-

(a) if the application was approved, issue a new permit in the name of the applicant; and

(b) if the application was refused-

(i) notify the applicant of the decision, in writing within 15 working days;

(ii) give written reasons for the refusal if required by the applicant; and

(iii) inform the applicant of his or her right to appeal against the decision.

**37. Consideration of and decision on permit amendment applications**

(1) On receipt of an application in terms of regulation 36 of these Regulations, an issuing authority-

(a) must consider whether the granting of the application is likely to adversely affect the environment or the rights or interest of relevant stakeholders;

(b) may for good reason amend or substitute any condition attached to a permit and any new information at the time of the amendment application; and

(c) may require the applicant to furnish additional information.

(2) A permit may be amended by-

(a) removing a condition;

(b) changing a condition;

(c) changing the quantity of the indigenous genetic and biological resources involved;

(d) removing or adding indigenous genetic and biological resources;

(e) adding specific permit conditions;

(f) updating or changing any contact details on the permit issued; or

(g) correcting a technical or editorial error on the permit issued.

(3) The issuing authority must promptly decide on the application if-

(a) the application is for a non-substantive amendment or interests of the stakeholder or stakeholders as contemplated in section 82 of the Act are not likely to be adversely affected; or

(b) If the application is for a substantive amendment, or if the environment or rights or interests of the stakeholder or stakeholders as contemplated in section 82 of the Act are likely to be adversely affected, the issuing authority, must before deciding on the application consider the relevant factors in Chapter 2 of these regulations.

(4) After having reached a decision on an application, the issuing authority must-

(a) notify the applicant of the decision, in writing within 15 working days;

(b) if the application was approved, issue an amended permit to the applicant; or

(c) if the application was refused-

(i) give written reasons for the refusal to the applicant; and

(ii) inform the applicant of his or her right to appeal against the decision of the issuing authority to the relevant appeal authority.

## CHAPTER 4
## MATERIAL TRANSFER AGREEMENTS, BENEFIT SHARING AGREEMENTS AND THE ADMINISTRATION OF THE BIOPROSPECTING FUND

### Part 1: Agreements

**38. Material transfer agreement**

(1) Parties to a material transfer agreement are the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) of the Act for the provision of access to the indigenous genetic and biological resources to which the application for any of the permits relates.

(2) A material transfer agreement must be in the prescribed format set out in Annexure 11 to these Regulations.

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

(4) If the stakeholder, that is party to the material transfer agreement, is a community, a community resolution authorizing a representative to enter into material transfer agreement, must be in the prescribed format set out in Annexure 13 to these Regulations.

**39. Benefit-sharing agreements**

(1) Parties to a benefit-sharing agreement are the applicant and the stakeholder or stakeholders contemplated in section 82(1)(a) and (b) of the Act for the provision of or access to the indigenous genetic and biological resources or associated traditional knowledge to which the application for any of the permits relates.

(2) If for whatever reason, the stakeholders contemplated in section 82(1)(a) and (b) of the Act, cannot be identified for the provision of or access to the indigenous genetic and biological resources to which the application for any of the permits relates, the Director-General must enter into a benefit-sharing agreement with the applicant.

(3) A benefit-sharing agreement contemplated in subregulation (2) must achieve one or more of the following benefits:

(a) conservation of the indigenous genetic and biological resources;

(b) support for further research on indigenous genetic and biological resources and traditional knowledge;

(c) enhancement of the scientific knowledge and technical capacity to conserve, use and develop indigenous genetic and biological resources;

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

(e) improve livelihoods of the communities and enhancement of technical capacity of the communities or individuals involved.

(4) A benefit-sharing agreement must be in the prescribed format set out in Annexure 12 to these Regulations.

(5) The Minister may refuse to approve a benefit-sharing agreement if it does not achieve one or more of the benefits contemplated in subregulation (3).

(6) Before approving a benefit-sharing agreement or any amendment to such an agreement in terms of section 83(2) of the Act, the Minister-

(a) must be satisfied that the benefit-sharing agreement is fair and equitable to all parties;

(b) may consult any person or persons competent to provide technical advice on the benefit-sharing agreement; or

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

(7) If the stakeholder, that is party to the benefit sharing agreement, is an indigenous community or community, a community resolution authorizing a representative to enter into benefit sharing agreement, must be in the prescribed format set out in Annexure 13 to these Regulations.

**Part 2: Administration of the Bioprospecting Trust Fund**

**40. The administration of the Bioprospecting Trust Fund**

(1) The Bioprospecting Trust Fund established in terms of section 85 of the Act must be managed by the Director-General in terms of the Treasury Regulations issued in terms of the Public Finance Management Act, 1999 (Act No. 1 of 1999).

(2) For the purposes of complying with the relevant provisions of the 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.

(3) The Director-General must-

(a) notify permit holders of any of the permits contemplated in regulations 14 and 15 of these Regulations of the banking details of the Bioprospecting Trust Fund, which details must be handed to such permit holders on issuance of any of the permits contemplated in regulations 14 and 15 of these Regulations;

(b) inform the parties to the benefit-sharing agreement of-

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

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

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

(4) The Director-General legal obligations in terms of subregulation (3) 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.

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

(a) to conserve the indigenous genetic and biological resources;

(b) to support further research on indigenous genetic 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 is fair and equitable;

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

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

(6) 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 subregulation (5) of these Regulations.

## CHAPTER 5
## GENERAL MATTERS

### 41. Offences

A person is guilty of an offence if that person-

(a) contravenes or fails to comply with a condition of a permit issued in terms of these Regulations;

(b) contravenes any provision of these Regulations;

(c) permits or allows any person to contravene any of the provisions of these Regulations;

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

(e) passes, uses, alters or has in his or her possession any altered or false document purporting to be a permit;

(f) knowingly makes any false statement or report for the purpose of obtaining a permit; or

(g) permits, or allows any other person to do, or to omit to do, anything which is an offence in terms of these Regulations.

### 42. Penalties

(1) A person convicted of an offence in terms of regulation 40 of these Regulations is liable to-

(a) imprisonment for a period not exceeding 10 (ten) years;

(b) a fine not exceeding 10 (ten) million rand; or

(c) both such a fine and such imprisonment.

(2) If a person is convicted of an offence involving bioprospecting or biotrading activities without a permit issued in terms of Chapter 7 of the Act, a fine may be determined, either in terms of subregulation (1) or equal to three times the commercial value of the activity in respect of which the offence was committed, whichever, is the greater.

### 43. Repeal of the Bioprospecting, Access and Benefit-Sharing Regulations, 2008

The Bioprospecting, Access and Benefit-Sharing Regulations published under Government Notice No. R. 138, in *Government Gazette* No. 30739 of 8 February 2008 is hereby repealed.

## CHAPTER 6

## Transitional Provisions

### 44. Continuation of regulated activities and permit issued in terms of the Bioprospecting, Access and Benefit-Sharing Regulations, 2008

(1) Anything done in terms of the Bioprospecting, Access and Benefit-Sharing Regulations, 2008 and which can be done in terms of these Regulations must be regarded as having been done in terms of these Regulations.

(2) Any permits issued in terms of the Bioprospecting, Access and Benefit-Sharing Regulations, 2008 that have not expired on the date of coming into effect of these Regulations, must despite the repeal of those Regulations be regarded as having been issued in terms of these Regulations, and remain valid until expiry date.

### 45. Pending applications and appeals lodged in terms of the Bioprospecting, Access and Benefit-Sharing Regulations, 2008

(1) An application for a permit submitted in terms of the Bioprospecting, Access and Benefit-Sharing Regulations, 2008 and which is pending when these Regulations take effect must be dispensed with in terms of these Regulations.

(2) An appeal lodged in terms of the Bioprospecting, Access and Benefit-Sharing Regulations, 2008, and which is pending on the date of coming into effect of these Regulations must be dispensed with in terms of the National Appeals Regulations.

### 46. Short title and commencement

These Regulations are called Bioprospecting, Access and Benefit-Sharing Amendments Regulations, 2015, and takes effect on a date published in the *Gazette.*

ANNEXURE 1
DISCOVERY PHASE NOTIFICATION FORM

ANNEXURE 2
APPLICATION FORM FOR A DISCOVERY PHASE EXPORT PERMIT

ANNEXURE 3
APPLICATION FOR AN EXPORT PERMIT FOR RESEARCH OTHER THAN BIOPROSPECTING

ANNEXURE 4
NON-REFUNDABLE FEES FOR PERMITS APPLICATION

ANNEXURE 5
APPLICATION FORM FOR A BIOPROSPECTING PERMIT OR BIOTRADE PERMIT OR INTEGRATED BIOTRADE AND BIOPROSPECTING PERMIT

ANNEXURE 6
DISCOVERY PHASE EXPORT PERMIT

ANNEXURE 7
EXPORT PERMIT FOR RESEARCH OTHER THAN BIOPROSPECTING

ANNEXURE 8
BIOTRADE PERMIT

ANNEXURE 9
BIOPROSPECTING PERMIT

ANNEXURE 10

INTEGRATED BIOTRADE AND BIOPROSPECTING PERMIT

ANNEXURE 11
MATERIAL TRANSFER AGREEMENT

ANNEXURE 12
BENEFIT-SHARING AGREEMENT

ANNEXURE 13
COMMUNITY RESOLUTION